The Snore-Breaker as a treatment for positional sleep apnea

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The intended result is the discovery of an more effective, more simple, cheaper and more user-friendly treatment for positional OSA than current therapies. Positional therapies have been used as regular treatment in the Amsterdam Wake Sleep Center....

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37780

Source
ToetsingOnline

Brief title
The Snore-Breaker as a treatment for positional sleep apnea

Condition

- Other condition

Synonym
OSAS, Sleep apnea

Health condition

Obstructieve slaap apneu stoornis (OSAS)

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: Amsterdam WaakSlaapCentrum van het Slotervaartziekenhuis,de fabrikant van de Snore-Breaker,De fabrikant van de Snore-Breaker, Nobel Trading

Intervention

Keyword: Positional OSAS, Positional therapy, Snore-Breaker

Outcome measures

Primary outcome

Primary dependent variable:

The primary study variable is the suitability of the Snore-Breaker as positional therapy for the treatment of OSA. A significant decrease in AHI (or even normalization of the AHI, an AHI <5) is the most important variable for assessing the efficacy of the Snore-Breaker. Other variables that are taken into account is a significant decrease of the time spent in the supine position and the total arousal index. The snoring index should not increase significantly and may even diminish. The above mentioned variables will be measured by a PSG. Another condition for the suitability of the SB is that SB causes few side effects and therefore will be tolerated (measured with the SAQLI questionnaire) and the patient, for this reason, will be compliant (measured by sleep diary and the therapietrouw-vragenlijst) to the SB.

Polysomnography (PSG):

The objective variables of OSA (the AHI, the snore index, the amount of time

spent in the supine position and the arousal index) will be measured with the aid of a standard PSG. The PSG is also used to exclude other sleep disorders and to measure the sleep structure. Using this PSG, the EEG,ECG, EMG, oxygen saturation, chest-abdominal breathing and mouth-nose breathing will be measured. There is also a measurement which is used to determine the sleeping position, and a microphone is attached to the neck in order to measure the snore index.

Secondary outcome

Secondary research variables:

The secondary variables include 1. the possible reduction of subjective OSA symptoms (excessive daytime sleepiness (measured by the ESS), snoring, excessive sweating at night, apneas, waking up coughing, waking up with a dry mouth / throat, difficulty breahting at night, waking up with a sour taste in the mouth, morning headaches (measured with the SLEEP-50)), subjective sleep quality (measured using the SLEEP-50), socially and functionally disabling consequences of OSA (as measured by SAQLI) and improving the Quality of Life (measured by the SF-36).

2. The possible learning effect (subjects sleeping less on their back as the treatmentperiod progresses) that occurs during use of the Snore-Breaker (measured by the data feedback from the SB) and

3. If the AHI, time in the supine position, the total arousal index, subjective symptoms and QoL significantly more improve with the vibrating-SB in comparison with the non-vibrating (placebo) SB and whether the vibrating SB triggers a significantly greater learning effect and is more user-friendly and has a

greater compliance.

Epworth Sleepiness Scale (ESS):

The ESS (Johns et al, 1992) measures the degree of daytime sleepiness (excessive daytime sleepiness; EDS). EDS is a common symptom of OSA. In this 8-item questionnaire the probability that the subject during the past two weeks has a tendency to doze is measured. The situations range from monotonic situations to activities where a high degree of attention is required. The interpretation of the ESS score is as follows: a score of 0-8 is considered normal, where as score of 9-12 displays mild sleepiness, 13-16 moderate and 17-24 severe excessive sleepiness.

SLEEP-50:

The SLEEP-50 (Spoormaker et al, 2005) is a 50-item sleep diagnosis questionnaire in which symptoms of various sleep disorders are mentioned. Among others; symptoms of sleep apnea, insomnia, narcolepsy, RLS / PLMD, a circadian rhythm disorder, somnabulisme, nightmares, slaapmisperception and hypersomnia are described. The impact it has on daily functioning, a possible mooddisorder and the factors that may have a bad influence on sleep are also inventoried.
The specific OSA symptoms which are mentionded are: snoring, excessive sweating at night, apneas, waking up while coughing, waking up with a dry mouth/ throat, having difficulty breathing at night, waking up with a sour taste in the mouth and morning headaches. Patients also have to score their average sleep, which measures the subjective sleep quality. At the beginning of the experiment, the

entire SLEEP-50 questionnaire has to be filled out in order to identify whether the subject has a comorbid sleep disorder, after each treatment period only the specific OSA symptoms together with the impact it has and the possible factors that have a bad influence on sleep are discussed. This questionnaire will measure if the specific OSA symptoms will reduce and if the subjective sleep quality will improve after treatment.

SF-36:

The Short Form (36) Health Survey (SF-36) is a validated questionnaire (Aaronson et al, 1998) that measures the general health status (quality of life, QoL) of the patient. The questionnaire measures the QoL as a result of a health problem on eight scales: physical functioning, social functioning, role limitations by physical problems, role limitations by emotional problems, mental health, pain and general health perception.

SAQLI:

The Calgary Sleep Apnea associated Quality of Life Index (SAQLI) questionnaire (Lacasse et al, 2002) consists of two sections that measure the effect of OSA on the QoL of the patient. The first part of the questionnaire consists of mapping the consequences of OSA. The questions measure four QoL parts: daily activities, social interactions, emotions and symptoms. In the second section of the questionnaire the patient must indicate whether he experienced side effects from the SB and how bad they were. Lastly, it is asked how much of a problem the side effects were in comparison with the advantages of the SB. In

this way, the usebality / tolerability of the SB is measured; when the side-effects form a moderate to major problem (or worse) in comparison with the benefits that the SB causes, the SB will then be defined as non-user friendly. An important addition of this questionaire is that besides the functional limitations because of OSA, also the socially debilitating consequences and the possible improvement of those consequences can be measured. The SAQLI is validated in English, so this questionnaire is translated into Dutch. This translation proved to be correct when a *back-translation* into English was performed. Therefore, the SAQLI can also be used as a validated questionnaire in Dutch.

Therapietrouw-vragenlijst:

The therapietrouw-vragenlijst is specially developed for this study. This questionnaire measures several variables. Compliance to a treatment is defined as using the therapy for at least four hours a night for at least 70% of the nights (Skinner et al, 2008). First, we investigated whether the subject has been compliant to the SB treatment and if not, what the reason was for not using the SB the entire night. In addition, we check whether the patient still suffers from symptoms for which he received the SB, if he suffers from side effects and what grade he would give the SB when the advantages and disadvantages are considered. An important question in this measurement is that it will be invertoried if the patient has stopped using the SB; because the SB was uncomfortable, because the patient thinks he has learned to sleep in other position except the supine position; or because he now uses another therapy for

his positional OSA. This questionnaire measures whether the SB is tolerated on the long term and if the patient is compliant to the treatment. In addition, the questionnaire serves as background to see what the possible underlying causes were for a poor compliance and if there possibly is a learning effect (according to the patient).

Sleep diary:

Each morning, the sleep diary, which consists of eight questions, has to be completed by the patient. Besides the subject number the time the patient goes to bed and gets up has to be filled out. The time that the patient falls asleep and (for the last time) wakes up that morning must also be filled out and whether they have worn the SB all night and if not, why they have not worn it the whole night. It is also measures how the subjects themselves felt how they had slept each night and how they felt during the day. The question 'Bijzondere omstandigheden' must be answered if there had been changes in sleep times, diseases, the environment, the standard alcohol, drug or cigarette use and why those changes occured. These changes can affect the number of apneas and the amount of time in the supine position that night. In this way sudden/once occuring changes in these variables may be explained by changes in their behavior which will be described under the question 'Bijzondere omstandigheden'. Using these questions, it can be checked daily if the patient is compliant and why they may not have used the SB and if necessary, be motivated to continue treatment.

Medications, diseases and weight:

Besides the fact that the AHI is worsened by alcohol, more apneas may occur when muscle relaxant medication is used, the patient has a cold or lung problems causing the breathing and the oxygen intake to reduce or when the patient has increased in weight. To check whether certain changes in the AHI are caused by the SB instead of changes in weight, current medications or illnesses, the current medications, diseases and weight will be inventoried at the start of the study (T1). In the following two visits (T2 and T3) it will be verified that no changes has occured in these three variables.

Data Feedback Snore-Breaker:

The SB registers every night, how often and how long the button of the SB is pushed. With these data it can be investigated how often the subject still lies on his back and if this amount decreases as the time progresses. In this way it can be examined whether a learning effect occurs by using the SB for a long period. By recording how long the button is pressed before the subject continues to sleep in another position, it can be researched (in the vibrating-SB) whether this change in sleeping position occured within 30 seconds (so before the SB starts o vibrate) so that the vibration has no additional value and secondly, and if the patient will rapidly get out of the supine position after longer use of the SB and the vibratingfunction has no additional value anymore.

Study description

Background summary

A obstructive sleep apnea (OSA) disorder is a sleep disorder that occurs predominantly in older age (Goncalves et al, 2004) and at 2 to 4 percent of people in middle age (Martin-Du Pan et al., 2004). OSA is defined as a sleep disorder where an obstruction in the mouth-/nasal cavity causes the patient to stop breathing (apnea) or to breath 30-50% less strongly (hypo-apnea) (Strollo et al, 1996) for at least 5 times per hour and causes the blood oxygen saturation to decrease at least 4% (Martin-Du Pan et al, 2004 and Strollo et al, 1996). The frequency of these apneas is translated in the apnea-hypo-apnea index (AHI) (Sin et al, 2002).

There is mild, moderate or severe OSA when the AHI, respectively is: 5-15, 15-30 or above 30 (Kwaliteitsinstituut voor de gezondheidszorg CBO, 2009). Some consequences of OSA are a significantly greater risk of car accidents (Rodenstein, 2009), hypertension, cardiovascular disease (McNicholas et al., 2007), metabolic changes (Levy et al., 2009), mental disorders (Sateia, 2009 and Sharafkhaneh et al., 2005) and depression (Akashiba et al., 2002 and Kawahara et al., 2005).

In addition to AHI above five OSAS, patients have the following objective symptoms: frequent drops in oxygen saturation in the blood, high sleep fragmentation, a disturbed sleep structure (too little deep or REM sleep), many awakenings (waking up and then fall asleep again), many Respiratory Event Related arousals (RERA's, an arousal is an acceleration in brain activity, when an arousal is caused by a breathing problem it is a RERA), many snoring-related arousals and a high total arousal-index (all arousals cumulated regardless the cause) (Ferguson et al., 1995).

Aside from the objective symptoms, OSA causes various subjective complaints. The specific OSA subjective symptoms include: excessive daytime sleepiness, (morning) headaches, waking with a dry throat or mouth, loud snoring and breathing stops (noted by the bed partner) (American Academy of Sleep Medicine, 2001). Other symptoms that OSA patients may experience are: excessive night sweating, palpitations, shortness of breath, waking startled, gasping for air, a sour taste in the mouth, sad / depressed feelings and mood swings. The cognitive skills are reduced in OSA (Decary et al, 2000) and patients with OSA have a significantly lower Quality of Life (QoL) (Kawahara et al, 2005, Lam et al, 2007, D 'Ambrosio et al, 1999, Lacasse et al, 2002, Llorberes et al, 2004, and Parish et al, 2003) and have more depressive symptoms (Akashiba et al 2002 and Kawahara et al, 2005) compared with controls.

Posture-dependent OSA is a common form of OSA which occurs in more than half of OSA patients (Berger et al, 1997 and Jokic et al, 1999). Patients suffer from

positional OSA when the AHI in the supine position is twice as high as the AHI in other postures. Positional OSA is associated with the classical OSA symptoms. A mouth brace (Mandibular Advancement Device; MAD) and treatment with Continuous Positive Airway Pressure (CPAP) can be prescribed for positional OSA. There are also specific treatments for these OSA-form, namely the position therapies. These position therapies consist of an object on the back that try to ensure that the patient no longer sleep in the supine position and, in this way, the patient no longer has apnoeas in the supine position and no longer suffer from OSA-related symptoms and consequences. There are various methods that may be used as a positional therapy. The methods vary from sewing a (tennis)ball in the back of the pajama (Kavey et al, 1985 and Berger et al, 1997), or binding another large object on the back (Jokic et al, 1999; Permut et al, 2010 and Skinner et al, 2008). This method is called the tennis ball technique. A newer, second kind of positional therapy consists of devices that beeps (Cartwright et al, 1985) or vibrate (Van Maanen et al, 2011) in the supine position.
The MAD and CPAP have side effects, suboptimal compliance and, in certain cases have to be paid by the patient himself. The effectiveness, usability and compliance (Bignold et al, 2009) of the positional therapies is also not yet optimal and little is known about the subjective improvement after treatment with a positional therapy. In this study, a new positional therapy , the Snore-Breaker (SB), will be tested. The SB has to be attached on the back and will vibrate when the patient lies on his back for more than 30 seconds. In this experiment we study 1. if the SB may be more effective, easier and has a better compliance than current treatments. It will also be investigated 2. if the use of the SB results in improvements in the subjective OSA-symptoms, the subjective sleep quality, functional and social deteriorating consequences of OSA and the QoL of the patient.

Little is known about the positional therapies that vibrates or beeps, and little research is carried out to investigate whether there is a learning effect which will occur through the use of these devices (Cartwright et al, 1985 and 1991). There is a learning effect when the user of the positional therapy will sleep less on his back when he uses the treatment for a longer period, so he learns to no longer sleep in supine position. This research will also investigate 3. whether the SB causes such a learning effect . There is only one study (Van Maanen et al, 2011) carried out which researched if the vibration is an important addition to the positional therapy. Therefore, this study investigates 4. whether the improvements were significantly greater when the SB vibrates compared to de SB without the vibrating function.

In this study, the effectiveness, tolerance, compliance, any improvement in subjective (OSA) symptoms, QoL and the potential learning effect of SB will be investigated. The SB belong to the second type of positional therapies. It will also be examined whether the vibration function of the SB is an important addition to the SB. The research questions in this experiment are defined as followed:

1. Is the Snore-Breaker a good treatment for positional OSA?
The SB is a good treatment when the SB significantly decreases the AHI, the amount of time in the supine position and the total arousal index and when the snoring (in all postures) does not significantly increase. In addition, the SB has to be tolerated well and the patient has to be compliant to the SB-therapy.

2. Does the SB improves the subjective (OSAS) symptoms, the subjective sleep quality, social/daily disfunctionalities and the QoL?

3. Does the Snore-Breaker cause a learning effect?

4. Is the vibration function is an important addition to the Snore-Breaker?
The vibration function is an important addition when the time in the supine position, the AHI, the total arousal index, the subjective symptoms and QoL are significantly more improved with the vibration function-SB in comparison with the non-vibrating SB and when the vibrating SB triggers a significantly greater learning effect and is more user-friendly and has a greater compliance.

Study objective

The intended result is the discovery of an more effective, more simple, cheaper and more user-friendly treatment for positional OSA than current therapies. Positional therapies have been used as regular treatment in the Amsterdam Wake Sleep Center. With this research we hope to discover a new device which is more user-friendly and more effective than current positional therapies, so it can be prescribed by the Wake Sleep Center of the Slotervaart Hospital.

This research will be an important contribution to scientific knowledge on positional therapies and about (the improvement of) positional OSA. There is little research done on this specific form of OSA and on the effectiveness, tolerance and compliance of the second kind of positional therapies. Additionally, this research will show whether subjective improvements occur after treatment of positional OSA. There is generally not much known about these possible subjective improvements and there is still no research done about the possible subjective improvements after the treatment with the second kind of positional therapies. Also, this research is the first experiment to evaluate the potential learning effect, measured each night instead of during 1 measurement. This allows the study with more certainty to show whether this learning effect exists and determine whether there is a gradual change in behavior in the sleeping position in which the patient is lying or if this behavioral change fluctuates every night in the study population.

This research seeks to discover a new positional therapy which is more effective, cheaper, and easier to use than the MAD, CPAP and the current positional therapies. Use of the tennis ball technique appears to be associated with poor compliance and the usability of the MAD and the CPAP also is suboptimal, which results in untreated positional OSA-patients on the long-term.

Besides treatment of patients with positional OSA, the SB may also be an important treatment for non-positional dependant OSA patients who become position dependant after weight reduction or after an Uvulopalatopharyngoplastiek (UPPP) operation. The SB can also be possibly used as a combination therapy in severe OSA because of the more severe apneas in the supine position and when OSA in the supine position remains despite the current therapy.

Study design

The study is a randomized single-blind crossover study, in which the effectiveness of a new positional therapy (the Snore-Breaker, in Intervention paragraph discussed in detail) is tested. The Snore-Breaker (SB) is equipped with a vibratingfunction (vibrating-SB). To level out the placebo effect and to investigate whether the SB without the vibratingfunction may work just as well as the vibrating-SB, each subject also received a placebo treatment in which the Snore-Breaker does not vibrate (placebo-SB). Each participant receives two treatments, in which the sequence of treatments is randomly chosen, so one half of the subjects will first receive the vibration-SB and the other half receives the placebo-SB as their first treatment. The patient should ware the Snore-Breaker every night while they sleep for a period of four weeks. Before the research is conducted, a PSG (PSG-1) without any treatment was carried out. The PSG is considered as the baseline for this research. On the last night of the first treatment period, a second PSG (PSG-2) will be carried out and the next morning after the PSG the subjects will receive the other treatment (placebo-SB when they first got the vibration-SB and vice versa). After the second treatmentperiod, another PSG (PSG-3) will be carried out. The results of the two PSG's after the treatment with a Snore-Breaker (PSG-2 and PSG-3) will be compared with the results of the baseline PSG-1, which has been carried out before the investigation is started. The researcher and the doctor are unaware of the order of treatments per patient. The patient on the contrary, will notice the order in which he receives the treatments simply because he feels the SB vibrating or not when he lies in supine position. Therefore, this is a single-blind randomized crossover study. The patient is told that it is important that he does not tell the order of their treatments. Because of possible bias that participants can develop when they know that the non-vibrating SB functions as a placebo, this is not told to the patient and they only know that we want to investigate which SB works best. The accompanying instruction booklet (stating that the SB really supposed to vibrate) is therefore not given, but the instructions are told to the patient during the interview and they are summarized on the inside of the SB-box. We chose a treatment period of 4 weeks, because after this time the subjects will be used to the positional therapy and because a washout period of at least a week is needed to minimize any carry-over effects (Skinner et al, 2008).

At the start of the experiment, the weight will be measured, and it is verified that this weight does not significantly differ from his weight during the

baseline PSG (PSG-1). In addition, diseases and the current medication use is recorded and it will be investigated whether these and other variables are in concordance with the inclusion criteria. When the patient can be enrolled for the study, the subject is given a subject number that is randomly chosen by the random number generator. All the patients who have an even subjectnumber will get SB1 as their first treatment and the patients with an odd number will get the SB2 as their first treatment. The manufacturer of the SB determined, using head or tail, if the vibrating-SB or the placebo-SB will be labeled as SB1. Only the manufacturer has got this information.

The PSG's measures the objective symptoms of positional OSA. In addition to these objective variables, also subjective symptoms will be measured by questionnaires. At the start of the experiment, several surveys will be conducted to measure the specific OSAS related complaints, the QoL, the subjective sleep quality, the functional and social limitations by OSA and the excessive daytime fatigue. The questionnaires taken at the start of the experiment are considered as the basline of the subjective variables. At the end of each treatment at the afternoon before the PSG, the same questionnaires are taken as a posttest. In this way, there will be examined whether the treatment causes a difference in the subjective symptoms. There are also additional questionnaires which should be filled out during the posttest. These additional questionnaires measure the possible side effects of the SB and how compliant the patients have been during the study. The subjects will receive a link to a website by email where a sleep diary should be filled out every morning throughout the study. This sleep diary keeps track of how long the patient has slept, if the patient has used the SB all night and the possible reason for not wearing the SB. In addition, with this sleep diary the subjective sleep quality of that night and whether the patient has smoked more, drank more alcohol or may have taken sleep medications that night, is measured. Because we only wish to measure the influence of SB on positional OSA and we do not want that a possible improvement in the OSA is caused by other measures, we recommend that the subjects do not alter their smoking habits, alcohol intake and sleep times.

The SB's are implemented with software, which registers every day for a period of 5 weeks, how often the button on the SB is pressed (for more than 2 seconds). In this way it is measured how often the patient lies on his back every night and does not count the times that the subject quickly (ie less than 2 seconds) press the button on the SB when he rolls over as he changes side to sleep. The SB also dayly records the average number of seconds the button is pressed before the patient turns of his back. Using these data, it can be examined whether subjects sleep less in supine position when the treatmentperiod progresses, so whether there is a learning effect and the patients almost / no longer lie on their backs.

Intervention

The Snore-Breaker:
The Snore-Breaker (SB) is a positional therapy. The device consists of an adjustable elastic band which have to be tied around the waist. A green disc will be attached to this elastic band and has to be placed on the back. The best height for the SB is just below the shoulder blades, with the disk resting upon the spine. The disc has a white button whcih is pressed when the patient is lying on his back. The press-side of the SB should face the bed. In the vibration-SB, the disk will vibrate when the button is pushed for more than thirty seconds, e.g. when the patient lies on his back for more than thirty seconds. The placebo-SB does not vibrate when the patient is sleeping in supine position. The vibration-SB has different vibration functions. When the subject still continues to lie on his back despite the vibration, the machine switches to a different vibration program. The device operates on a battery voltage of up to 4.5 V and is therefore harmless. According to the manufacturer of the SB (Nobel Trading) only twenty of the 750 sold SB were returned, it can therefore be suggested that the SB is well tolerated and easy to use.

Study burden and risks

The burden of this study (compared to the regular treatment) consists of an extra night sleep study (PSG) in the hospital. This visit will take approximately 16 hours. The patient also visits the hospital for 1 hour for an interview and to sign the informed consent. In addition, the subjects must complete several questionnaires and have to follow the recommended treatment for eight weeks. The questionnaires include questions about sleep, sleep problems, daytime dysfunctional consequences, the QoL and the Snore-Breaker. The subjects are tested for positional OSA and comorbid sleep disorders using a PSG. During the intake interview weight, drugs, medication and alcohol use, comorbid epilepsy, pulmonary, cardiovascular, psychiatric and memory problems are discussed, which often are already known in our database before the start of this study.

Advantages: In this study, a direct therapeutic effect is intended by the patients. It is expected that the use of the Snore-Breaker will effectively treat the positional OSA and that the patient recovers from his OSA-related symptoms and consequences.

There are no known risks and side effects of the (vibrating) positional therapies. A possible risk would be a worsening of sleep apnea (which will disappear when the intervention is discontinued) and possible worsening of nocturnal restlessness during the course of this investigation. Conducting this research in comparison with the associated burden/risks and benefits for subjects related to participation, is in my view justified because the subjects will be appropriately treated for their diagnosed sleep apnea. Also, the patients will be tested afterwards to evaluate if the treatment if effective, and in this way it may be concluded that the subject should continue the treatment. In this way, the subject is (probably) effectively treated for his

sleep apnea, which is accomplished by this research and what I believe outweighs the burden / risks associated with participating in this research.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Positional sleep apnea. With a total apnea-hypoapnea index (AHI) of 5 or higher. An AHI in supine position of 5 or higher. An AHI in other sleeping positions of 10 or lower. The AHI in supine position has to be at least two time as big as the AHI in other positions.

Exclusion criteria

People who already have another therapy for their sleep apnea (such as a MAD or CPAP) and who have AHI scores which do not meet the inclusion criterea will be excluded. Also, people who (continually) use sleepmedication or alcohol- and drugsabusers will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2012
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	The Snore-Breaker
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-04-2012
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL39249.048.12