Autoset S11 For Her versus Autoset S11 standard in women with symptomatic OSA; Do women with OSA treated with Autoset For Her have a better improvement in sleep-related impairment compaired to Autoset standard . A randomized clinical Trial of an Intervention

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The objective of this study is to find out whether women with OSA treated with Autoset For Her experience a greater improvement in sleep-related problems compared to the Autoset standard.We also want to investigate whether the pressure is higher…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON56434

Source
ToetsingOnline

Brief title
AFOHER

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
obstructive sleepapnea, OSA

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Amphia academie via wetenschapsfonds

Intervention

Keyword: Autoset For Her, complaints, OSA, women

Outcome measures

Primary outcome

Sleep related impairment

Do women with OSA treated with Autoset For Her have a better improvement in

sleep-related impairment compaired to Autoset standard (measured by - Quality

of life (PROMIS® 1.3Global02) which content next subjects:

- - Social functioning (Promis® 2.0, ability to participate in social roles and

activities short form 4A)

- - Physical functioning (PROMIS® 2.0 physical functioning short form 8b)

- - Anxiety (PROMIS®, Anxiety short form 4a)

- - Depression (PROMIS® 1.0 Depression short form 4A)

- - Fatigue (PROMIS® 1.0 fatigue short form 4A)

- - Pain (PROMIS® 1.0 Numerical Assessment Score Pain Intensity

- - Problems with Sleep Disorders (PROMIS®, 1.0)

Secondary outcome

- The difference in adherence/duration of use of CPAP therapy after 10 weeks

for the total group with distinction between Autoset FH and standard Autoset

- Comfort by Visual Analog Scale (VAS)

- Reason for stopping CPAP for the entire group and distinction between pre- and postmenopausal women

• CPAP infidelity; Despite maximum guidance, CPAP is not applied by the patient or for insufficient time.

• CPAP intolerance; CPAP is not well tolerated based on side effects and/or psychological aversion.

• CPAP effectiveness failure; CPAP has insufficient physiological effect: the AHI is not sufficiently lowered.

• failure of CPAP symptoms; CPAP has sufficient physiological effect, but insufficient symptomatic effect. (OSA Adult Guideline, NVALT 2018) -.

- The difference in CPAP pressure between Autoset FH and Autoset standard after 10 weeks (95% pressure)

- ESS (Questionnaire *ESS*) (Appendix)

Study description

Background summary

Nevertheless, little research has been done to date on the effect of CPAP on the reduction of complaints such as mood swings, insomnia and daytime

functioning in women with symptomatic OSA.
In addition, it is not known whether less women stop using the Autoset For Her compared to the standard AutoseIn recent years. More attention has been paid in the media and among doctors to the fact that men and women show differences. The number of women with OSA is increasing, which means that more knowledge and insight is needed to provide women with better tailored treatment.

We use the autoset S11, which has both the standard and the For Her (FH) algorithm

In 2021 visited 1800 patients the outpatient clinic of the Center for Sleep Medicine Amphia, with the diagnosis of sleep apnea. There were 1150 men and 650 women. We see an increase in the number of women who report complaints that may be consistent with sleep apnea.

Until now, little research has been done into the effect on symptoms and compliance of Continuous Positive Airway Pressure (CPAP) in women with obstructive sleep apnea (OSA). Many studies of symptomatic OSA have been conducted in a predominantly male population.

Resmed has developed a CPAP algorithm specifically for premenopausal women with sleep apnea; Autoset For Her (FH) (S10-FH/ S11 FH = both devices have the same algorithm) (from now on it will be referred as S11), the algorithm of this CPAP device also responds to flow limitations and not only to the hypopneas and apneas. Flow limitations are more likely to give rise to arousals in premenopausal women. This means that S11 FH rises with pressure earlier than the standard S11, which should ensure that women sleep better and wake up less quickly, although they have less complaints. A 2015 study shows that for women the algorithm works just as well on a decrease in AHI as standard CPAP [28].

In addition, it is not known whether women experience more comfort from the device and fewer women stop using the Autoset For Her compared to the standard Autoset. In recent years, more attention has been paid in the media and among physicians to the fact that men and women show differences. The number of women with OSA is increasing, which means that more knowledge and insight is needed to provide women with better tailored treatment.
We are also curious whether this algorithm also has a positive effect on the postmenopausal group.
We use the Autoset S11, which has both the standard and the For Her algorithm.

Study objective

The objective of this study is to find out whether women with OSA treated with Autoset For Her experience a greater improvement in sleep-related problems compared to the Autoset standard.

We also want to investigate whether the pressure is higher with the S11 FH compared to the S11, the comfort of both devices, effect in complaints, which group has more dropouts (with reason) and what the operating time is for both devices.

Study design

RCT Autoset FH versus Autoset

Protocol

1. Inclusion criteria: women, AHI >=5, 18-71 yrs, daytime sleepiness (ESS >= 10 or by history) and/or other OSA-related complaints such as insomnia, daytime functioning difficulties, mood swings, fatigue , CPAP as a treatment
Exclusion criteria: unwilling to cooperate, unable to understand what the questionnaires contain

2. Informed consent
Provide patient information letter,
After consent: sign informed consent with OSAS nurse

3. Randomization via Castor

4. Baseline characteristics:
Age, AHI, premenopausal/postmenopausal, BMI, neck circumference, race, premenopausal/postmenopausal, ODI (oxigen desaturation index), ESS (Epworth sleepiness scale)

5. Complete questionnaires (PROMIS) before starting CPAP via Castor

6. Call after 2/3 days by the OSAS nurse; first questions are answered and questions are asked about the first nights with CPAP

7. Appointment OSAS nurse after 3 weeks for reading and discussion about use, problems and opportunity to ask questions. CPAP reading last week = T1

8. Complete questionnaires (PROMIS) 1 day before the appointment with the practitioner via Castor

9. Appointment with therapist and OSAS nurse after 10 (+/- 1 week) weeks: evaluation of therapy, fill in adherence (T2;2 weeks before and 95% pressure), read AHI and possibly the reason for failure, comfortscore APAP
End study

Intervention

group 1: S11 FH
group 2: S11

randomised startification
per arm 8 blocks: 8 x 10 participants
1 block of 10 is divided into postmenopausal / premenopausal, with 6 participants in the postmenopausal arm; with an additional distribution of 3 x S11 FH and 3 x S11 standard
4 participants in the premenopausal arm, with an additional distribution of 2 x S11 FH and 2 x S11 standard

Study burden and risks

Load: extra 2 times 10 minutes for completing the questionnaires
Risks: none, equipment has been extensively tested.

The study by Cross et al. (2006) shows that a titration with PSG in the clinic or a titration at home with CPAP shows an equally good score and pressure setting. We choose to hospitalize patients at home until an adequate pressure is found
.
The said questionnaires and software of the readout program have a predictive validity, it can be said with some certainty that the patients have an improvement on the outcome measures

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

women, AHI >=5, age between18-71, demonstrable daytime sleepiness (ESS >=10 or by anamnesis) and/or other OSA-related complaints such as insomnia, difficulty in day time functioning, mood swings, fatigue and CPAP as treatment

Exclusion criteria

Unable to understand what the questionnaires contain and/or not willing to cooperate.
Younger than 18 and older than 70 years

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-05-2024
Enrollment:	186
Type:	Actual

Medical products/devices used

Generic name:	autoCPAP (autoset S11 for her)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-11-2023
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL81844.015.23
Other	W23-033