Integrated Overactive Bladder Clinical Trial in clinical practice III

Published: 09-05-2012
Last updated: 28-04-2024

Primary objectives of INTACT III are:1) to prospectively compare the efficacy of Sacral Nerve Stimulation (SNS) with BOTOX® 100 U related to the Patient Perception of Bladder Condition (PPBC) questionnaire (Coyne 2006) and the reduction of urinary...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON38014

Source
ToetsingOnline

Brief title
INTACT III

Condition

- Bladder and bladder neck disorders (excl calculi)
- Renal and urinary tract therapeutic procedures

Synonym
bladder overactivity, urgency

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: farmaceutische en medische industrie bedrijven,Medtronic B.V.

Intervention

Keyword: clinical practice, clinical trial, integrated, overactive bladder

Outcome measures

Primary outcome

* outcome measures related to primary objectives:

**The proportion of patients who have a treatment response of improvement of at least 2 categories on the PPBC (Coyne 2005) (Appendix 14). As stated before, the power calculation to define the sample size for this study is based on the PPBC

**Number of episodes of urinary urgency incontinence as registered in the 3 day micturition diary (Appendix 8).

References

Coyne KS, Zyczynski T, Margolis MK, Elinoff V, Roberts RG. Validation of an overactive bladder awareness tool for use in primary care settings.

Adv Ther. 2005 Jul-Aug;22(4):381-94

Secondary outcome

Related to secondary objective 1 (see chapter 2 Protocol)

- Intensity of urgency scale (Patient Perception of*Intensity of Urgency Sensation (PPIUS)) (Cartwright 2010) (Appendix 12)

- Mean absolute change in number of voids/24 hrs (3-days micturition diary)

- Volume involuntary loss of urine (from 3-days micturition diary)

Related to secondary objective 2 (see chapter 2)

- Urinary Incontinence-Specific Quality-of-Life Instrument Dutch (I-QOL)

(Appendix 11) Total score change from baseline, subscale change from baseline

- PRAFAB (Impact and severity of urinary incontinence) (Appendix 9) Total score

change from baseline

Related to secondary objective 3 (see chapter 2 Protocol)

- Patient's satisfaction

- Percentage patients with a positive response on "Behandeling Baat Schaal" .

(score is 1 or 2, i.e., "fors verbeterd"or "verbeterd".

References:

Cartwright R, Srikrishna S, Cardozo L, Robinson D. Patient-selected goals in

overactive bladder: a placebo controlled randomized double-blind trial of

transdermal oxybutynin for the treatment of urgency and urge incontinence. BJU

Int 2010; July 7 [Epub ahead of print]

Study description

Background summary

In the Netherlands many persons suffer from Overactive Bladder Syndrome (OABs) or shortly Overactive Bladder (OAB). After stress urinary incontience with a prevalence of 49%, is it the most prevalent lower urinary tract complaint (17%). OAB might, especially in case of complaints of urgency urinary incontinence (UUI), limit profoundly the patient 's quality of life. According to recent data more than 5% of all women might have UUI, while half of these women really suffer because of it. This means that in the Netherlands more than 300000 women have UUI. When also those with mixed urinary incontinence will be

taken into account, there are more than 1 miljon. The ICS defines OAB as a disfunction of the bladder during the filling/storing phase when during an (ambulatory) urodynamic investigation involuntary contractions of the bladder can be demonstrated while the patient tries to surpress these. Patients have strong compelling urgency to void, visit frequently the toilet (frequency), feel the urency need to go to the toilet during the night (nocturia) (symptoms of urgency and frequency, without urinary incontinence are called 'OAB dry') and have, based on urgency, involuntary loss of urine (urgency, frequency with urinary incontinence are called 'OAB wet'). These symptoms migth occur seperately or in combination. An OAB patient produces often small volumes of urine (< 150 ml.), pointing at a smaller functional capacity of the bladder. Often this might lead to extensive loss of urine, up to a complete loss of urine out of the bladder. This has a dramatic impact on the emotional and moral feelings of those affected by this. Especially young women OAB has a hugh impact. The most important effect of UI in man is 'the feeling of being out of controle' while in women in general 'the feeling of the need to take precautions' might be the most important factor related to the subjective experience of the impact of the loss of urine (Teunissen 2005).

Costs for incontinence absortion materials (IAM) are about ¤ 300 per person per year (CvZ: GIPeilingen 2007). In case there is no adequate intervention the need to use IAM is permanent. While costs of IAM return every year, despite the fact that effective treatment might be expensive, treatment might be efficient for the long term. Costs for society are even much higher because of indirect costs related to absence of work and environnement such as collection and destroying IAM. For 2006 total annual Dutch economical costs for only incontinence absortion materials were calculated to be > ¤ 163 miljons (CvZ: GIPeilingen 2007).

Rationale for botulinum toxin injections and sacral neuromodulation
In case patients develop intractable symptoms, until not too long time ago, the only remaining option was major reconstructive surgery such as bladder augmentation with the aim of increasing the capacity of the bladder. In addition to the risk of a major surgical procedure, complications such as metabolic disorders and chronic retention are common and these procedures do not guarantee continence. Consequently, this is generally considered an option of last resort that is appropriate only for a very small minority of patients (Chartier-Kastler 2007).Therefore, for the vast majority of patients with OAB and UUI who do not benefit from anticholinergic therapy, pelvic physiotherapy or PTNS, acceptable effective treatment options after failed conservative therapy are needed.

Nowadays, implantable neuromodulation systems, such as sacral neuromodulation or Sacral Nerve Stimulation (SNS) are available.
Clinical trials suggests that SNS has sustained efficacy in a well selected population of patients with refractory OAB, with moderate risks of procedure related complications. SNS seems to be a safe, reversible and minimally

invasive therapy that does not preclude other treatment options. This therapy might be an efficacious alternative to more invasive techniques. Although SNS has the potential to become a well established treatment option in the Netherlands, this therapy is not widely available so far. Reasons for this are high costs of the device and procedure and the occurrence of technical difficulties (Janknegt et al, 2001).
Also the use of Botulinum Type A (primarily BOTOX®) for OAB populations has been reported. A few randomized controlled trials in idiopathic patients who have not been adequately managed with conservative therapy have investigated its efficacy, safety and durability (Brubaker, 2008; Sahai, 2007). These studies support the potential utility of BOTOX® for patients with idiopathic OAB.

So, Sacral Nerve Stimulation, as a minor invasive surgical intervention, and botulinum toxin injection therapy for the treatment of OAB are momentarily filling the gap between conservative treatment and major invasive surgery. So far, SNS has already been registered in the Netherlands. Up to now, for the indication OAB botulinum toxin injection therapy is not (yet) registered in the Netherlands. Moreover, it seems that the injections only have a temporarily efficacy and therefore must be repeated periodically each 6-9 months. For these reasons it might be that SNS has superior efficacy to botulinum toxin injection therapy and is more safe than the other option. To increase our knowledge and to get more insight into this question we want to compare the efficacy and safety of SNS with botulinum toxin injection therapy in adults patients with idiopathic OAB.

References:
Teunissen TAM, Weel van C, Lagro-Janssen ALM. Urinary incontinence in older people living in the community examining helpseeking behaviour. Br J Gen Pract 2005; 55: 776-82.

Health Insurance Board/CVZ. GIPeilingen 2007. Ontwikkelingen genees- en hulpmiddelengebruik; 2008 august. Report No.: nr. 29.

Chartier- Kastler E. Sacral Neuromodulation for treating the symptoms of OAB and non-obstructive UR: >10 years of clinical experience. 2007 BJU International

Janknegt RA, Hassouna MM, Siegel SW, et al. Long-term effectiveness of sacral nerve stimulation for refractory urge incontinence. Eur Urol 2001; 39(1): 101-106

Brubaker L, Richter HE, Visco A, Mahajan S, Nygaard I, Braun TM, Barber MD, Menefee S,
Schaffer J, Weber AM, Wei J; Pelvic Floor Disorders Network. Refractory idiopathic urge urinary incontinence and botulinum A injection. J Urol. 2008 Jul;180(1):217-22. Epub 2008 May 21

Sahai A, Khan MS, Dasgupta P. Efficacy of botulinum toxin-A for treating idiopathic detrusor overactivity: results from a single center, randomized, double-blind, placebo controlled trial. J Urol. 2007 Jun;177(6):2231-6

Study objective

Primary objectives of INTACT III are:

1) to prospectively compare the efficacy of Sacral Nerve Stimulation (SNS) with BOTOX® 100 U related to the Patient Perception of Bladder Condition (PPBC) questionnaire (Coyne 2006) and the reduction of urinary incontinence episodes (as measured with the 3 days micturition diary in patients with idiopathic OAB with urinary incontinence whose symptoms have not been adequately managed with conservative therapy, i.c. anticholinergic therapy or pelvic physiotherapy or PTNS.

2) to prospectively compare adverse effects of Sacral Nerve Stimulation (SNS) with BOTOX® 100 U.

Measurements will be executed after week 12 after the (first) treatment, after 6 and 12 months after treatment.

Secondary objectives of INTACT III
1) to prospectively compare the efficacy of Sacral Nerve Stimulation (SNS) with BOTOX® 100 U related to a decrease of urgency (as measured with the PPIUS questionnaire measuring decrease of patient*s perception of urgency), decrease of frequency (number of voids/24 hrs as measured with the 3 days micturition diary) and reduction volume involuntary loss of urine (as measured with the 3 days micturition diary,
2) to prospectively compare the efficacy of Sacral Nerve Stimulation (SNS) with BOTOX® 100 U on quality of life (as measured with the Incontinence Quality of Life Questionnaire (I-QoL), and on impact and severity of urinary incontinence (as measured with the PRAFAB questionnaire (Hendriks 2007)
3) to prospectively compare the efficacy of Sacral Nerve Stimulation (SNS) with BOTOX® 100 U on patient *s satisfaction as measured with the *patient satisfaction questionnaire*, and on patient*s impression of improvement (as measured with the *Behandeling Baat Schaal*,
in patients with idiopathic OAB with urinary incontinence whose symptoms have not been adequately managed with conservative therapy, i.c. anticholinergic therapy or pelvic physiotherapy or PTNS.

Measurements will be executed after week 12 after the (first) treatment, after 6 and 12 months after treatment.

Clinical hypotheses
SNS is more effective than BOTOX® 100 U as assessed by the difference between treatment groups in the proportion of idiopathic OAB patients with a positive

treatment response on the Patient Perception of Bladder Condition (PPBC) at Week 12 after (first) treatment and at 6 months and at 12 months after treatment.

SNS is more effective than BOTOX® 100 U improving the symptoms of idiopathic OAB as measured by the difference between treatment groups in the reduction of urinary incontinence episodes at Week 12 after (first) treatment and at 6 months and at 12 months after treatment.

Study design

Overall study design
In case of a new signed informed consent, and in- and exclusion criteria fulfilled, unsuccessful patients after INTACT II (progress less than two categories on the PPBC or < 50 % less Incontinence episodes frequency (IEFs) may enter INTACT III (see Flowchart 1). The setting of INTACT III is the region of South- Limburg, with participation of GPs and urologists, with study support from the PcCM of MUMC+.

This will be a mono-centre, single-blind, randomized, pragmatic, parallel-group study to assess the efficacy and safety of SNS (Group 1) compared to a single treatment of BOTOX® (Group 2) followed by a second treatment (if applicable) with BOTOX® (Group 2) in patients with idiopathic OAB with urinary incontinence whose symptoms have not been adequately managed with conservative therapy, i.c. anticholinergic therapy or pelvic physiotherapy or PTNS.
Following a qualification period of 3 to 6 weeks, patients meeting the study inclusion/exclusion criteria will be randomly assigned to one of two treatment arms (SNS or BOTOX® 100 U) in a ratio of 1:1 with a random permuted block size of four. To conceal treatment allocation, an independent research assistant prepared a computer-generated randomisation list and treatment allocation. In case of randomization to Group 1 the department of urology and the Pelvic care Center Maastricht of MUMC will perform the SNS, if randomized to Group 2 botox injections will be performed at the department of urology of MUMC. Patients will be stratified according to the number of urgency incontinence episodes reported at baseline, <= 9 or > 9 episodes, over the 3-day micturition diary completed during the qualification period. Because there can be differences in underlying causes of the health problem OAB in relation to gender patients will be stratified according to gender as well.
Patients in group 2 will be eligible to receive a second BOTOX® treatment if all the predefined Treatment 2 criteria are met (see Section 5.9.2.5).

One randomization number will be assigned to each patient prior to the first treatment and will be associated with one of the following treatment sequences:
A) Group 1: SNS
B) Group 2: BOTOX® 100 U (Treatment 1)/BOTOX® 100 U (Treatment 2)
Patients will be followed regularly for safety and efficacy at post-treatment visits, Week 15/16 and Week 52 post treatment in both groups and in Group 2

also at Week 24-27 and Week 40. In both groups follow-up is 52 weeks. Patients in Group 2 will complete up to 3 treatments, in case the first and/or the second treatment was not sufficiently successful (see section 5.9.2.5 for qualification for Treatment 2 (Botox 2)) with a maximum study participation duration of 52 weeks (if a patient qualifies for Treatment 2 (Botox 2) at week 24 and received Treatment 2 (Botox 2) at week 27, and - if necessary - qualified for Treatment 3 (Botox 3) at week 51 and received Treatment 3 (Botox 3) at week 52).

Total duration of the complete study (INTACT I, II & III) is 4 years.

Estimation of problems to be expected
There are no big problems with respect to diagnostics and therapy to be expected. All methods used are usual care diagnostical and treatment procedures. Phase 3 has an experimental character because of the randomisation procedure, and only outcome measures based on micturition diaries and questionnaires are used. Besides the urodynamic investigation and the cystoscopy, both regular, in general acceptable but invasive diagnostical procedures, especially the treatment methods during phase 3 are invasive. But, based on literature and own experience we do not expect major problems regarding this.

For further information about the study design of phase 3, please see Appendix 20.

Intervention

INTERVENTION PHASE 3 = INTACT III

In case of insufficient success within the identified protocollized period phase 3 of the study will follow. The urologist will choose between SNS and botox injections. For this project this means randomization between SNS and botox injections. SNS treatment and botox injections will be executed in the MUMC. If cured the patient will also have evaluations at 6 and 12 months. For treatment with botox see paragraphs 'Treatment procedure' and 'Intervention' of het INTACT III protocol (Appendix 20).

SNS
SNS is a rehabilitative treatment to be used to treat selected patients with OAB (Siegel 2000, Aboseif 2007) . In this technique, low-intensity electrical impulses are generated by an implantable neurostimulator (INS) (also referred to as an implantable pulse generator (IPG)), and delivered via a conducting electrode to one of the lower sacral nerves (usually S3) involved in the control of lower urinary tract function.
SNS treatment is based on the protocol that has been (partly) developed within the department of urology of the MUMC+. This has been described in the document

Nieuwe DBC Urologie Neuromodulatie met een geïmplanteerd neurostimulatie systeem voor de behandeling van patiënten met functistoornissen van de lagere urinewegen (Messelink et al. 2008). For more details see paragraphs 'Treatment procedure' and 'Intervention' of het INTACT III protocol (Appendix 20).
The neurostimulator will be programmed and interrogated externally by the physician with a magnetic programming device. With the use of the hand-held patient programmer, the patient can stop and start the INS, as well as increase and decrease the amplitude of the stimulation. Before the system is permanently implanted, a test with a permanent lead (two-stage procedure) will be carried out to identify whether or not the candidates is suitable for the permanent implant. The test phase will lasts 1-6 weeks. The patient qualifies for permanent implant if during the test phase, the patient reports at least 50% improvement in the micturition diary variables and lower urinary tract symptoms (as recorded in the micturition diary). The permanent implant of the system is by a minimally invasive technique which will be performed at the *Dagcentrum* of the MUMC.

Botox injections
Each vial of BOTOX® (Botulinum ToxinType A) Purified NeurotoxinComplex, (formulation no. 9060X), contains: 100 units (U) of Clostridium botulinum toxinType A, 0.5 mg albumin (human), and 0.9 mg sodium chloride in a sterile, vacuum-dried form without a preservative. One unit (U) corresponds to the calculated median lethal intraperitoneal dose (LD50) in mice. The botulinum toxin injections will also be administred at the *Dagcentrum* of the MUMC+. A flexible or rigid cystoscope may be used for study treatment administration. BOTOX® injections are administered as a minimally invasive technique which will be performed at the *Dagcentrum* of the MUMC. The urologist will receive one 10 mL syringe pre-filled with 10 mL of study medication and one 1 mL syringe pre-filled with saline from the independent reconstitutor. The 10 mL of study drug will be administered as 20 injections each of 0.5 mL.

References
Bent AE, Gousse AE, Hendrix SL, Klutke CG, Monga AK, Yuen CK et al. Validation of a two-item quantitative questionnaire for the triage of women with urinary incontinence. Obstet Gynecol. 2005;106:767-73

ZonMw final report. The effects of involving a nurse practitioner in primary care for adult patients with urinary incontinence.
Programme DoelmatigheidsOnderzoek 2003-2006 Subsidy round round 04, 2008

Faber E, Custers JWH, Berghmans LCM, van Dongen JJAM, Van Groeningen COM, Grupping-Morel MHM et al. Landelijke Eerstelijns Samenwerkings Afspraak Incontinentie voor urine. Huisarts Wetensch. 2007;:50:S9-S12

Ref Botox

Messelink EJ, Heesakkers JPFA, van Koeveringe GA, Koldewijn EL. Neuromodulatie met een geïmplanteerd neurostimulatie systeem voor de behandeling van patiënten met functiestoornissen van de lage urinewegen. Dossier Nieuwe DBC Urologie Juni 2008

Study burden and risks

The following risks van occur during the study period

urinary retention for which CIC is required

increased PVR for which CIC is required in case of the following criteria:
**Patient has a PVR of >= 350 mL (regardless of symptoms), OR
**Patient has a PVR >= 200 mL and < 350 mL and the patient reports associated symptoms i.e. voiding difficulties, sensation of bladder fullness that in the investigator*s opinion require CIC

urinary tract infection (UTI)
An adverse event of UTI will be recorded if both the following criteria are fulfilled, regardless of patient symptoms:
**A positive urine culture result with a bacteriuria count of >105 CFU/mL
**Leukocyturia of >5/hpf

hinder/oversensibility/pain at location of tined lead of permanent SNS implant or infection/inflammation at those sites

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

OAB patients eligible for SNS and botulinum toxin type A
To be included in the study, the MUMC + urologist will check whether or not the patient meets the following criteria at recruitment/assessment:
1. Patient, who after non-successful INTACT I and II or was a non-responder to conservative treatments as specified in INTACT I and to PTNS as specified in INTACT II, was referred to a MUMC+ urologist.
2. Written informed consent has been obtained.
3. Written documentation has been obtained in accordance with local privacy requirements, where applicable.
4. Patient is male or female, aged between 18 and 75 years old (Amundsen 2005).
5. Patient weighs >= 40 kg.
6. Patient has symptoms of idiopathic OAB (frequency and urgency) with urinary incontinence immediately prior to qualification, determined by documented patient history.
7. Patient experiences a mean of 3 episodes of urinary urgency incontinence in the 3-day patient bladder diary completed during the qualification period (qualification day -14 to start treatment day 1)
8. Patient experiences urinary frequency, defined as an average of >= 8 micturitions (toilet voids) per day i.e. a total >= 24 micturitions in the 3-day patient micturition diary completed during the qualification period (qualification day -14 to start treatment day 1).
9. Patient has a negative pregnancy test result if female and of childbearing potential.
10. Patient has a negative urine dipstick reagent strip test at start treatment day 1 (for nitrites, blood and leukocyte esterase) and, in the investigator*s opinion, patient is asymptomatic for UTI on day of treatment.
11. Patient is able to complete study requirements including using the toilet without assistance, is able to collect volume voided per micturition measurements over a 24- hour period, complete micturition diaries and questionnaires, and attend all study visits in the opinion of the coordinating investigator.

Exclusion criteria

OAB patients not eligible for SNS and botulinum toxin type A
1. residual urine after micturition > 100 cc determined using sonography or catheterisation.
2. presence of urinary tract infection (UTI), determined using urinary sticks. (temporarely until UTI has been solved by antibiotics, then still potential candidate)
3. patient has symptoms of overactive bladder due to any known neurological reason (eg, spinal cord injury, multiple sclerosis, cerebrovascular accident, Alzheimer*s disease, Parkinson*s disease, etc)
4. patient has a predominance of stress incontinence in the opinion of the coordinating investigator, determined by patient history
5. patient has received anticholinergics or any other medications or pelvic physiotherapy or PTNS to treat symptoms of overactive bladder, including nocturia, within 3 months of start treatment day 1.
6. patient uses chronic intermittent catheterisation (CIC) or indwelling catheter to manage his or her urinary incontinence
7. patient has been treated with any intravesical pharmacologic agent (eg, capsaicin, resiniferatoxine) within 12 months of start treatment day 1
8. patient has history or evidence of any pelvic or urological abnormalities, bladder surgery or disease, other than *overactive bladder*, that may affect bladder function including but not limited to:
bladder stones and/or bladder stone surgery at the time of*qualification or within 6 months prior to qualification
surgery (including minimally invasive surgery) within 1 year of qualification for: stress incontinence, uterine prolapse, rectocele, or cystocele
9. patient has a history of interstitial cystitis/painful bladder syndrome, in the opinion of the coordinating investigator
10. patient has an active genital infection, other than genital warts, either concurrently or within 4 weeks prior to qualification
11. patient has a history or current diagnosis of bladder cancer or other urothelial malignancy, and/or has un-investigated suspicious urine cytology results. Suspicious urine cytology abnormalities require that urothelial malignancy is ruled out to the satisfaction of the investigator according to local site practice.
12. patient is male with previous or current diagnosis of prostate cancer or a prostate specific antigen (PSA) level of > 10 ng/L at screening. Patients with a PSA level of >= 4 ng/L but <= 10 ng/L must have prostate cancer ruled out to the satisfaction of the investigator according to local site practice
13. patient has evidence of urethral and/or bladder outlet obstruction, in the opinion of the coordinating investigator at qualification or start treatment day 1.
14. patient has had urinary retention or an elevated PVR urine volume that has been treated with an intervention (such as catheterization) within 6 months of qualification. Note: voiding difficulties as a result of surgical procedures that resolved within 24 hours are not exclusionary.
15. patient has a 24-hour total volume of urine voided > 3000 mL, collected over 24 consecutive hours during the 3-day bladder diary collection period prior to treatment day 1.
16. patient has a history of 2 or more urinary tract infections within 6 months of qualification.

17. patient has a serum creatinine level > 2 times the upper limit of normal at qualification.
18. patient has current or previous un-investigated hematuria. Patient with investigated hematuria may enter the study if urological/renal pathology has been ruled out to the satisfaction of the investigator.
19. patient has hemophilia, or other clotting factor deficiencies, or disorders that cause bleeding diathesis.
20. patient cannot withhold any antiplatelet, anticoagulant therapy or medications with anticoagulant effects for 3 days prior to start treatment day 1. Note: some medications may need to be withheld for > 3 days, per clinical judgment of the investigator.
21. patient has a known allergy or sensitivity to any components of the study medication, such as the active ingredients botulinum toxin type A or the inactive ingredients human albumin and sodium chloride or has had a known allergic reaction to any other botulinum toxin product such as Myobloc®, Dysport® or Xeomin® (Allergan Pharmaceuticals 2010), or antibiotics to be used during the study.
22. females who are pregnant, nursing or planning a pregnancy during the study or females of childbearing potential who are unable or unwilling to use a reliable form of contraception during the study (see Section 6.3)
23. patient is currently participating in or has previously participated in another therapeutic study within 30 days of qualification (or longer if local requirements specify).
24. the urologist first preference is a treatment with anticholinergics/antimuscarinics;- Use of anticoagulant medications (eg, warfarin and other coumadin derivatives), antiplatelet medications (eg, clopidogrel and aspirin [including low dose]) and any other medications with anticoagulative effects (eg, non-steroidal anti-inflammatory drugs [NSAIDs]) within a period 3 days (or longer according to the clinical judgment of the ccordinating investigator) prior to any study treatment

Study design

Design

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

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-11-2012
Enrollment:	166
Type:	Anticipated

Medical products/devices used

Generic name:	sacral neuromodulation
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	BOTOX® (Botulinum Toxin Type A) Purified Neurotoxin
Generic name:	Botox (Allergan), formerly botulinum toxin type A, is now onabotulinumtoxinA
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-05-2012
Application type:	First submission
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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
EudraCT	EUCTR2011-001484-50-NL

Register	ID
CCMO	NL36363.068.11