The efficacy of botulinum toxin A injection in pelvic floor muscles in chronic pelvic pain patients: a double-blinded randomised controlled trial

Published: 07-07-2017
Last updated: 13-04-2024

The objective of this study is to investigate whether BTA injection in the pelvic floor muscle is an effective treatment for patients with chronic pelvic pain and pelvic floor hypertonicity.

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

Summary

ID

NL-OMON48791

Source
ToetsingOnline

Brief title
Botulinum toxin A injection in pelvic floor muscles

Condition

- Other condition
- Muscle disorders
- Soft tissue therapeutic procedures

Synonym
chronic pelvic pain, pelvic floor muscle hypertonicity

Health condition

chronische bekkenpijn

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: botulin, hypertonicity, pelvic floor muscles, pelvic pain

Outcome measures

Primary outcome

Decrease of chronic pelvic pain, measured with a decrease in visual analog scale score (VAS score 0-10) with 33% and the PGI-I of 6 or 7 (better or much better).

Secondary outcome

- Quality of life measured with validated questionnaires: patient global impression of improvement score (PGI-I), pelvic floor distress inventory (PFDI-20), pelvic floor impact questionnaire (PFIQ-7), quality of life (EQ-5D), paindetect, pain catastrophizing scale (PCS), hospital anxiety and depression scale (HADS), sexual function (FSDS, FSFI).
- Decrease of pelvic floor hypertonicity measured by the MAPLe device
- Patient preference study: evaluating patient preferences in maximal treatment effect at cost of possible side-effects.

Study description

Background summary

Chronic pelvic pain is common, affecting 15% of women aged 18-50 [Mathias]. Pelvic floor muscle spasms resulting in chronic pelvic pain may occur as a primary event or secondary to a physical, psychological or pathological factor. First-line treatment consists of pelvic floor physiotherapy. When first-line treatment fails, more invasive interventions can take place. One described intervention is injection with Botulinum toxin A (BTA) in the pelvic floor muscles. It produces a localized, partial, and reversible chemical denervation of the muscle which results in localized muscle weakness or paralysis. The is some evidence that injection of BTA in the hypertonic pelvic floor muscles decreases pelvic pain in patients with therapy resistant chronic pelvic pain, however this is not investigated in a randomized controlled trial.

Study objective

The objective of this study is to investigate whether BTA injection in the pelvic floor muscle is an effective treatment for patients with chronic pelvic pain and pelvic floor hypertonicity.

Study design

Double-blinded randomized placebo-controlled cross-over trial

Intervention

The pelvic floor muscles will be injected with either 100 IU BTA or NaCl 0.9% (placebo).

Study burden and risks

Patients will undergo one of two vaginal injections with BTA or placebo. To evaluate efficacy, questionnaires and physical examination will be performed at baseline, t=4, 8, 12, and 26 weeks after injection. The discomfort will mainly be during the injection, this will last for maximal 15 minutes. Risks of injection will be bleeding or infections which are anticipated by hemostatic pressure and antiseptic workflow and are considered minimal. Side-effects as temporarily urinary and/or fecal incontinence will be discussed before inclusion (0-6%).

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

- Female, >16 years
- Chronic pelvic pain according to the ICS with or without dyspareunia
- Vaginal examination with one finger possible
- Pelvic floor hypertonicity measured by physical examination by registered pelvic floor physiotherapist
- Previous physical therapy with registered physical therapist was unsuccessful
- Good understanding of Dutch language
- Willing to provide informed consent

Exclusion criteria

- (wish for) Pregnancy/lactation during study period
- Previous pelvic floor botox treatment
- Known hypersensitivity to botox
- History of neuromuscular or bleeding disorders

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-01-2020
Enrollment:	94
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	botox
Generic name:	botulin toxin A
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	07-07-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-06-2019
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-07-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-10-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-10-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2017-001296-23-NL
CCMO	NL61409.091.17