GON-injection for a sooner and better treatment of cluster headache: a double-blind randomized controlled trial

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Primary ObjectiveTo provide a definitive answer regarding the efficacy of GON-injection as first-line prophylactic therapy in episodic cluster headache, by showing that GON-injection decreases the mean total dose of verapamil needed during the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48495

Source
ToetsingOnline

Brief title
CHIANTI

Condition

- Other condition

Synonym
Cluster headache; Horton's neuralgia

Health condition

Hoofdpijn

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Hersenstichting en het Innovatiefonds Zorgverzekeraars

Intervention

Keyword: Episodic Cluster headache, Greater Occipital Nerve, Prophylactic treatment

Outcome measures

Primary outcome

The primary endpoint of this study is total dose of verapamil used during the

study period

Secondary outcome

Secondary study parameters

- Median number of days to remission (7 consecutive days without attack)

- Mean number of attacks per day during the study period

- Peak dose verapamil

- Premature termination of study due to need for prophylactic escape medication

Tertiary study parameters

- The total use of attack medication. (For the total study period and each of

the three consecutive 4-week time periods)

- Mean number, severity (1-10) and duration of attack per day. (For the total

study period and each of the three consecutive 4-week time periods)

- Percentage of patients that are attack-free at days 7, 14 and 28

- Occurrence of *non-cluster* headache (number of days and mean intensity per

affected day; For the total study period and each of the three consecutive

4-week time periods)

- Adverse events

- Subjective feeling at days 7, 14 and 28 (visual analogue scale, VAS)

- Satisfaction score (7 point scale, higher scores are better)

Additional endpoints at days 2 and 28, and at the end of the 12-week study

period:

- Would the patient recommend this treatment to others?

- What treatment does the patient think he/she received

(placebo/GON/uncertain)?

- What treatment do the investigators think the patient has had?

Study description

Background summary

Cluster headache is a very severe primary headache disorder. In episodic cluster headache, attacks occur in *bouts* (clusters) lasting weeks to months. Management of cluster headache entails a combination of attack and prophylactic treatment. Current first choice prophylactic treatment (verapamil) has considerable side effects which can be serious and include possibly fatal cardiac arrhythmias; and it can take weeks to titrate to an effective dose. Evidence has emerged that local steroid injection of the greater occipital nerve (GON) may be effective in cluster headache, but this method has not been investigated as a first line prophylactic treatment in a large, well-documented group of episodic cluster headache patients who are still free of prophylactic medication and just entered a new cluster headache episode. As such, GON-injection has not yet found its way into current treatment protocols. We plan to perform this multicentre double-blind randomized controlled trial to investigate whether GON-injection is efficacious as a first-line prophylactic treatment, aiming to remove the need for high doses of daily medication - such as verapamil - with associated side effects.

Study objective

Primary Objective
To provide a definitive answer regarding the efficacy of GON-injection as first-line prophylactic therapy in episodic cluster headache, by showing that GON-injection decreases the mean total dose of verapamil needed during the treatment of a cluster episode in episodic cluster headache.

Secondary/Tertiary Objectives:
- To Show that the addition of GON-injection leads to
o Faster attack-freedom (7 consecutive days without attacks) than the current standard treatment with verapamil only.
o Less side-effects than the current standard treatment with only verapamil.
o A decrease in attack frequency, severity and duration of attacks (and thus a decrease in the use of attack medication) compared to the current standard treatment with verapamil only.
- To learn how long the beneficial effects of GON-injection will last.
- To show that GON-injection will lead to higher patient satisfaction scores, compared to the current standard treatment with only verapamil.

Study design

Multicentre, randomized, double-blind placebo-controlled study with 12 weeks follow-up.

Intervention

In addition to the standard treatment with oral verapamil (start 120 mg extended release and increased if necessary according to current clinical practice), patients will be allocated to one of 2 study-treatments:
[I] Occipital placebo saline injection (n=40)
[II] GON-injection (n=40)

Study burden and risks

In this study, there is no great (extra) burden end there are no significant risks expected. Patients will start regular treatment for a cluster headache episode (verapamil, according to the current clinical standard); and in addition to this they will either receive a GON injection with steroids or a placebo injection with saline. We expect only minor, local side effects from both types of injection.

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

- Patients have to be diagnosed with episodic cluster headache according to the international classification of headache disorders - third edition, ICHD-3
- Patients have to be aged 18 years or older
- Patients need to be newly diagnosed and treatment naïve, or already diagnosed and currently free from prophylactic treatment
- Patients need to have a mean of 1 or more attacks per day in the 3 days preceding inclusion.
- Patients should be in their cluster period for shorter than 4 weeks before inclusion.

Exclusion criteria

- A contraindication for treatment with steroids or verapamil
- The use of anticoagulants or known bleeding disorder.
- Use of any prophylactic medication for cluster headache
- Patients with a history of other primary headache who are currently using prophylactic medication for this headache

- Pregnancy

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:	Recruitment stopped
Start date (anticipated):	30-07-2019
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Depo-Medrol
Generic name:	methylprednisolone acetate
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	20-12-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

Approved WMO

Date:	07-05-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	09-03-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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	EUCTR2018-002224-17-NL
CCMO	NL67197.058.18