Repeated corticosteroid injections around the Greater Occipital Nerve (GON) as prophylactic treatment in chronic cluster headache

Published: 12-04-2022
Last updated: 25-09-2024

This study has been transitioned to CTIS with ID 2024-514311-10-00 check the CTIS register for the current data. The primary objective is to determine if repeated GON-injection result in effective control of cluster headache attacks for more months...

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

Summary

ID

NL-OMON56462

Source
ToetsingOnline

Brief title
Repeated GON injections in CCH / REGON

Condition

- Headaches

Synonym
Clusterheadache, Trigeminal Autonomic Cephalalgias

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Chronic cluster headache, GON injections, Greater Occipital Nerve block

Outcome measures

Primary outcome

Primary outcome measure: Retention rate (= time between the first injection and end-of-treatment; survival curves verum vs. placebo)

Secondary outcome

Secondary outcome measures (verum vs. placebo):

- Frequency of daily cluster headache attacks
- The use of acute attack medication per day (subcutaneous sumatriptan and 100% oxygen)
- Mean duration and severity (1-10) of attacks
- Injection interval
- Total number of injections in study period
- Proportion of participants still in study at 1 year
- Participants idea: did they receive placebo or verum?
- Physician*s idea: did they administer placebo or verum?
- Adverse events + ultrasound structural integrity measurements greater occipital nerve
- Proportion of subjects with a >50% and 100% reduction in attack frequency
- Daily quality of life (EQ 5D)
- Healthcare use & productivity losses

Study description

Background summary

A single injection of the greater occipital nerve (GON) with corticosteroids (*GON-injection*) has been shown to be efficacious for the prophylactic treatment of cluster headache, with only mild, local side effects and often has its effect within days. It is a low-cost and safe treatment option; however, the beneficial effects are limited to weeks to months. This makes the injection suitable for episodic cluster headache, where periods with headache attacks last weeks to months. However, the effect of repeated GON-injections has never been studied in a double-blind randomized trial as a prophylactic therapy in a well-documented group of chronic patients. As such, (repeated) GON-injection has not yet found its place in current (inter)national treatment protocols for chronic cluster headache. The injection is often only used as a last-resort treatment in a very limited number of headache centres in a trial-and-error approach with a treatment interval varying between 3 and 6 months. It is, therefore, not known what chronic cluster headache patients can expect from this treatment.

Study objective

This study has been transitioned to CTIS with ID 2024-514311-10-00 check the CTIS register for the current data.

The primary objective is to determine if repeated GON-injection result in effective control of cluster headache attacks for more months compared to placebo in chronic cluster headache.
Secondary objectives are to determine:
- If the effect of one GON-injection predict the effects of subsequent GON-injections.
- The median GON-injection interval.
- The tolerability of repeated GON-injections .
- Structural integrity of the GON after the study period.

Study design

Bi-centre, randomized, double-blind, placebo-controlled retention trial with a maximum follow-up of one year.

Intervention

The verum group will receive a GON-injection with 80mg methylprednisolone suspension. The placebo group will receive 2 ml of saline. Efficacy will be assessed with weekly attack journals and structural integrity of the GON will

be assessed with ultrasound imaging.

Study burden and risks

When effective, repeated GON-injections will decrease the need for high doses of prophylactic treatment with its associated high risk of side effects in chronic cluster headache patients. The burden is relatively low, since follow up will include non-invasive ultrasounds of the GON, and GON-injections, according to the study protocol. Furthermore, a weekly attack journal and three, monthly, online questionnaires will be administered. No serious side effects were reported in previous studies regarding (repeated) greater occipital nerve injection, with only minor (local) side effects. In conclusion, we feel that the risks are very small since GON-injection is already proven safe in previous studies.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age >=18
- Chronic cluster headache (International Classification of Headache Disorders
- third edition; ICHD-3)
- Ictal pain must be always at the same side
- >=4 weekly attacks of cluster headache in the prospective one-month baseline observation period
- On a stable regimen of cluster headache prophylactics for >4 weeks prior to onset of study treatment and agreeing not to increase the dose and not starting a new cluster prophylactic during the study period

Exclusion criteria

- Contra-indication against, or current use of, corticosteroids
- Occipital nerve stimulation (ONS)
- Use of anticoagulation medication or a known bleeding disorder
- Inability to use an electronic diary to monitor individual attacks and other items
- Other headaches if the patient cannot reliably distinguish them from attacks of cluster headache
- Current use of prophylactic medication for other headaches
- 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:	Recruiting
Start date (anticipated):	07-03-2023
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Depo-medrol suspension
Generic name:	Methylprednisolonacetate
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	12-04-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-07-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	09-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-04-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	03-05-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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
EU-CTR	CTIS2024-514311-10-00
EudraCT	EUCTR2021-006687-25-NL
CCMO	NL79665.058.22