Blink reflex changes after GON-injection in cluster headache: Clinical and pathophysiological implications.

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To investigate if the GON-injection affects trigeminal threshold and transmission using the R2 component of the blink reflex.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Headaches
Study type	Observational non invasive

Summary

ID

NL-OMON49065

Source
ToetsingOnline

Brief title
Blink reflex changes after GON-injection in cluster headache / BREACH

Condition

- Headaches

Synonym
Hortons neuralgia, Suicide headache

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Beat The Beast

Intervention

Keyword: Blink reflex, Cluster headache, GON-injection

Outcome measures

Primary outcome

The primary endpoint of this study is the difference in mean ipsilateral R2 latency of the blink reflex between the one-week and baseline timepoint.

Secondary outcome

* Clinical response to GON-injection as measured by daily attack frequency, attack intensity and duration

* The association between the mean ipsi- and contralateral R2 latency of the blink reflex and the clinical response, as measured in percentage change in attack frequency, to the GON-injection

* The association between the mean ipsi- and contralateral AUC of the blink reflex and the clinical response to the GON-injection

* The change in ipsi- and contralateral mean R2 latency and mean AUC between all 4 time points

* The difference in mean trigeminal sensible and pain threshold between all 4 time-points

* The association between trigeminal sensible and pain threshold and clinical response to the GON-injection

Study description

Background summary

Cluster headache is a very severe primary headache disorder. At present, the pathophysiology of cluster headache is unknown. Three key components have been identified, the trigeminovascular system, the parasympathetic nerve fibers and the hypothalamus, but the exact cause of the disease remains to be identified. Management of cluster headache entails a combination of attack and prophylactic treatment. Evidence has emerged that local steroid injection of the greater occipital nerve (GON) may be effective in the prevention and prophylactic treatment in cluster headache. The mechanism of action of GON-injection is not clear. We aim to investigate the mechanism of action and possible predictive parameters of effect by assessing trigeminal nerve transmission and local sensory and pain threshold. We will use the blink reflex, more specifically the R2 component of the blink reflex, as a way of measuring the trigeminal nerve transmission.

Study objective

To investigate if the GON-injection affects trigeminal threshold and transmission using the R2 component of the blink reflex.

Study design

Single center, prospective cohort study with 12 weeks follow-up.

Intervention

GON-injection (as part of regular treatment)

Study burden and risks

The risks of the proposed study are very low. The blink reflex is a electrophysiological measurement and has been conducted since the 1970s. The current and voltage required for the measurements are extremely low. If patients agree to participate, participants need to spent 2 hours extra on the first visit (in which the GON-injection will be administered) when the first two measurements will be conducted. The third visit can be simultaneous with a consultation with their neurologist to evaluate the effect of the GON-injection.
This study can provide valuable new insights in the therapeutic effect of the GON-injection and can hopefully increase our knowledge of cluster headache pathophysiology.

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 or chronic cluster headache according to the international classification of headache disorders * third edition, ICHD-3
- Patients have to be aged 18-75 years
- Patients should be receiving a GON-injection as regular therapy for episodic or chronic cluster headache

Exclusion criteria

Treatment with a SPG-stimulator or an occipital nerve stimulator

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-10-2020
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	17-08-2020
Application type:	First submission
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
CCMO	NL71803.058.19