Role of propranolol in the treatment of migraine

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20883

Source
Nationaal Trial Register

Brief title
TREPMI

Health condition

Migraine/Migraine
Iontophoresis/Iontoforese
CGRP
Propranolol

Sponsors and support

Primary sponsor: Dr. A.H. van den Meiracker,
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Source(s) of monetary or material Support: Erasmus Medical Center

Intervention

Outcome measures

Primary outcome

change in forehead dermal blood flow

Secondary outcome

change in heart rate

change in blood pressure

bloodlevels of propranolol

Study description

Background summary

Prophylactic drugs are used by migraineurs. The most commonly recommended prophylactic drugs are the betablockers.
Among the different betablockers,
propranolol is one of the most commonly prescribed for migraine prophylaxis. It is not known how betablockers
decrease the frequency of migraine attacks, but it is thought that it may affect the brain serotonin receptors. Previously it has been demonstrated that the activation of serotonin receptors leds to the blockade of
CGRP liberation.
We hope to determine the role of propranolol in the prophylaxis of migraine by measuring with a laser Doppler scanner
the increase in dermal blood flow (DBF) after stimulation of the afferent nerves of the trigeminal nerve on the forehead.
The trigeminal nerve has also innervations to the dura mater, which is thought to be involved in the origin of migraine.
In order to accomplish that, the trigeminal afferent nerves will be stimulated by topical application of capsaicin and
electrical stimulation. Both stimuli lead to the release of CGRP, a vasodilator neuropeptide. We have the hypothesis, that
in migraine patients, the use of propranolol may modify the release of this neuropeptide. We will investigate this
hypothesis with the above mentioned model. First we will perform a study with healthy volunteers and in future, we hope

to perform in migraine patients with an effective prophylactic response and with an absent prophylactic response to
propranolol.
This study will provide more insight in the mechanism of action of propranolol and possibly in the pathophysiology of
migraine, which hopefully will also shed light on therapeutic targets and improved migraine treatment .

Study objective

Reduced dermal blood flow response to capsaicin application and saline iontophoresis after propranolol ocompared to placebo administration.

Study design

subject have to come twice to the Erasmus MC, with a time interval of 1 till 2 weeks

Intervention

Administration of propranolol

Contacts

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Eligibility criteria

Inclusion criteria

Age between 18 and 64 years

Male or female

Females should use an oral contraceptive pill (the measurements will be held during any moment of the month, except during the week without pill) or Mirena

Non-smoking for > 6 months

Body mass index between 19 and 28 kg/m2

Capable and willing to give informed consent

General good health, based on medical history and physical examination

Exclusion criteria

History of cardiovascular disease

History of migraine

Previous history of asthma or use of bronchodilators.

Blood pressure <110 systolic (sitting)

Heart rate <60 bpm

Perimenopausal status of females

Any serious illness that can compromise study participation

Use of any medication (e.g., NSAIDs, other analgesics) < 48 hrs before the study

Dermal diseases at the upper frontal side of the face

Pregnancy or breastfeeding

History of sensitivity to the fruits of capsicum plants (e.g. chilli peppers)

Alcohol or drug abuse

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-03-2016
Enrollment:	22
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5765
NTR-old	NTR6007
Other	EudraCT : 2016-000279-26

Study results