Trigeminovascular effects of propranolol in migraine treatment

Published: 30-03-2016
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To determine the mechanism of action of propranolol in the prophylactic treatment of migraine.

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

Summary

ID

NL-OMON43388

Source
ToetsingOnline

Brief title
TREPMI

Condition

- Headaches

Synonym
Migraine

Research involving
Human

Sponsors and support

Primary sponsor: Inwendige Geneeskunde
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: capsaicin, iontophoresis, migraine, propranolol

Outcome measures

Primary outcome

Changes in dermal blood flow response to capsaicin application and saline

iontophoresis, after propranolol intake.

Secondary outcome

Changes in blood pressure after propranolol use.

Study description

Background summary

Prophylactic drugs are used by migraineurs. The most commonly recommended prophylactic drugs are the beta-blockers. Among the different beta-blockers, propranolol is one of the most commonly prescribed for migraine prophylaxis. It is not known how beta-blockers 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

To determine the mechanism of action of propranolol in the prophylactic treatment of migraine.

Study design

A randomized double blind controlled cross over study

Intervention

Oral administration of propranolol 80mg (oral solution)

Study burden and risks

The amount of time consumed by this research and the side effects of propranolol are the burden. Capsaicin application can cause temporary redness and some irritation of the skin.

Contacts

Public
Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age between 18 and 64 years
Non-smoking for more than 6 months
Females should use an oral contraceptive pill
Body mass index between 19 and 28 kg/m^2
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, as well as during 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-02-2017
Enrollment:	22
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Propranolol
Generic name:	Propranolol hydrochloride

Ethics review

Approved WMO Date:	30-03-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-03-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2016-000279-26-NL
CCMO	NL56536.078.16

Study results

Date completed: 18-02-2019

Results posted: 09-05-2019

Actual enrolment: 22

First publication
01-01-1900