Role of propranolol on migraine treatment

No registrations found.

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

Summary

ID

NL-OMON21229

Source
NTR

Brief title
TREPMI

Health condition

Migraine
CGRP
Propranolol
Iontophoresis/Iontoforese
Capsaicin/Capsaïcine

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Changes in dermal blood flow response to capsaicin application and saline iontophoresis, after propranolol administration.

Secondary outcome

Blood pressure changes after propranolol use.

Study description

Background summary

Migraine is one of the top 10 most disabling diseases. Propranolol is a nonselective β-blocker that is primarily used to treat hypertension and there is high-quality evidence that propranolol is also an effective prophylactic drug for migraine headaches. The mechanism of action of propranolol is still unknown. We hope to determine the mechanism by measuring with a laser Doppler scanner the increase in dermal blood flow after stimulation of the afferent nerves of the trigeminal nerve on the forehead. The trigeminal nerve also innervates the dura mater, where the migraine is thought to have its origin. We hypothesized that the propranolol will inhibit the rise of dermal blood flow caused by capsaicin application and saline iontophoresis. This will provide more insight in the action of propranolol, resulting in a better understanding of the pathophysiology of migraine and also in its prophylactic treatment.

Study objective

The administration of propranolol will inhibit the increase in dermal blood flow (DBF) induced by capsaicin application.

Study design

The volunteers will come twice to Erasmus MC. Each appointment will last an estimated of 150 minutes.

Intervention

The volunteers will need to take a tablet of Propranolol 80mg (which is the normal

therapeutic dose)

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

• Non-smoking for > 6 months

• Body mass index between 19 and 30 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

• Blood pressure <110/70 (supine)

• 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):	01-03-2016
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	NL4466
NTR-old	NTR5708
Other	EudraCT : 2016-000279-26

Study results