

Role of propranolol in the treatment of migraine

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20883

Bron

Nationaal Trial Register

Verkorte titel

TREPMI

Aandoening

Migraine/Migraine
Iontophoresis/Iontophorese
CGRP
Propranolol

Ondersteuning

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Overige ondersteuning: Erasmus Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

change in forehead dermal blood flow

Toelichting onderzoek

Achtergrond van het onderzoek

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 leads 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 .

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Administration of propranolol

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-03-2016
Aantal proefpersonen:	22
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5765
NTR-old	NTR6007
Ander register	EudraCT : 2016-000279-26

Resultaten