Does oral administration of dabigatran etexilate, a direct thrombin inhibitor, achieve clinical significant concentrations of dabigatran and thrombin inhibiting activity in vitreous and subretinal fluid?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23085

Source
NTR

Brief title
Dabigatran & Ocular Accessibility

Health condition

Rhegmatogenous retinal detachment.

Sponsors and support

Primary sponsor: Het Oogziekenhuis Rotterdam
Rotterdams Oogheelkundig Instituut
Source(s) of monetary or material Support: Combined Ophthalmic Research Rotterdam (CORR)

Intervention

Outcome measures

Primary outcome

Levels of dabigatran in vitreous, subretinal fluid and plasma.

Antithrombin activity in vitreous and subretinal fluid and plasma.

Secondary outcome

None.

Study description

Background summary

Coagulation factor thrombin is thought to play an important role in the development of proliferative vitreoretinopathy (PVR). The direct thrombin inhibitor dabigatran is therefore an interesting potential drug candidate. It is investigated whether oral administration of dabigatran etexilate (single dose, 220 mg) in patients with a rhegmatogenous retinal detachment leads to clinical significant dabigatran levels and thrombin inhibiting activity in the vitreous and subretinal fluid. During surgery, a vitreous or subretinal fluid sample will be taken, and a blood sample.

Study objective

Oral administration of dabigatran etexilate in patients with a rhegmatogenous retinal detachment leads to clinical significant dabigatran levels and thrombin inhibiting activity in the vitreous and subretinal fluid.

Study design

Perioperative.

Intervention

Dabigatran etexilate (Pradaxa®) 220 mg once 2, 4 or 8 hours before surgery.

Contacts

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Eligibility criteria

Inclusion criteria

- Age > 18 years

- Informed consent

- Needing surgery for a rhegmatogenous retinal detachment (scleral buckle surgery or vitrectomy).

Exclusion criteria

- Using other anticoagulants (e.g. acenocoumarol, heparin etc)

- Using medication that increases risk of GI bleeding (e.g. aspirin, NSAIDs, SSRIs, oral corticosteroids).

- History of stomach ulcer/ bleeding

- Patients with renal function (CrCL) < 50 mL/min

- Age > 75 years

- Hepatic impairment

- Hypersensitivity to the active substance or to any of the excipients

- Concomitant treatment with systemic ketoconazole, cyclosporine, itraconazole, tacrolimus and dronedarone

- Lesion or condition at significant risk of major bleeding

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2014
Enrollment:	24
Type:	Actual

Ethics review

Positive opinion

Date:	30-09-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40980
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4673
NTR-old	NTR4825
CCMO	NL48418.078.14
OMON	NL-OMON40980

Study results

Summary results
Mulder VC, Kluft C, van Etten PG, La Heij EC, van Meurs JC. Higher vitreous concentrations of dabigatran after repeated oral administration. Acta Ophthalmol. 2017; 95(4): e345-e346.