Pain from intraocular injections with ultrathin needles compared to regular needles.

Gepubliceerd: 04-01-2013 Laatst bijgewerkt: 18-08-2022

Intravitreal injections are used more and more frequently in ophthalmology. This trend is mostly caused by the arrival of anti-VEGF agents used for age-related macular degeneration, diabetic macular edema and macular edema secondary to retinal vein...

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

Samenvatting

ID

NL-OMON29404

Bron
NTR

Aandoening

intravitreal, intraocular, injection, pain, crossover.
intravitreaal, intraoculair, injectie, pijn.

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre
Overige ondersteuning: Radboud University Nijmegen Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pain score on 100mm numeric rating scale.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Pain and discomfort at the injection site are common side effects of intravitreal injections with bevacizumab. In current practice 30 gauge needles are regularly used for these intravitreal injections and they have been shown to cause less pain than thicker needles.

Objective:

The main objective of this study is to evaluate whether pain caused by intravitreal bevacizumab injections with the regular 30 gauge needle can be reduced by using a 33 gauge needle.

Study design:

Double-blind, randomized, cross-over trial.

Study population:

Patients eligible for treatment with two consecutive injections with intravitreal bevacizumab.

Intervention:

All patients receive two consecutive intravitreal injections with bevacizumab 1.25 mg in 0.05 ml as decided by their treating physician. Patients are randomized to receive the first intravitreal injection either with the regular 30 gauge or the 33 gauge needle. The interval for the second injection will be 2-6 weeks and will be performed using the alternate injection needle.

Study endpoints:

The primary outcome is the degree of pain during the intravitreal injection, as measured on a

100 mm numeric rating scale (NRS) of pain intensity. The secondary endpoint is anxiety experienced during the injection procedure determined using the hospital anxiety depression scale (HADS) and the state-trait anxiety inventory (STA-I).

Burden and risks associated with participation:

Patients are asked to fill in a HADS and STA-I questionnaire prior to the two consecutive injections and to score the degree of pain experienced during the intravitreal injections on a 100 mm NRS immediately after the procedure. There are no known risks associated with a higher needle gauge. Patients will be informed of the risks related to the injection procedure itself, namely endophthalmitis, retinal detachment and increased risk of cataract, which are the same as in normal clinical practice and are unlikely to be associated with needle gauge.

Doel van het onderzoek

Intravitreal injections are used more and more frequently in ophthalmology. This trend is mostly caused by the arrival of anti-VEGF agents used for age-related macular degeneration, diabetic macular edema and macular edema secondary to retinal vein occlusion. It is known from clinical practice that discomfort and pain at the injection site are common side effects from intravitreal injections. In current practice 30 gauge needles are often used for intravitreal injections with bevacizumab and they have been shown to cause less pain and vitreal reflux than thicker needles. We expect pain level can be lowered even further by reducing needle width to 33 gauge.

Onderzoeksopzet

Injection nr 1 at timepoint 0 and injection nr 2 after 1 month.

Onderzoeksproduct en/of interventie

Two consecutive intraocular bevacizumab injections with a 33G and 30G needle.

Contactpersonen

Publiek

Philips van Leydenlaan 15
F. Asten, van
Nijmegen 6525 EX
The Netherlands
+31 (0)24 3610241

Wetenschappelijk

Philips van Leydenlaan 15
F. Asten, van
Nijmegen 6525 EX
The Netherlands
+31 (0)24 3610241

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with an indication for at least two consecutive monthly intravitreal injections with bevacizumab.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients unable to state pain levels or give written informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	10-01-2013

Aantal proefpersonen:	75
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	NL3611
NTR-old	NTR3770
Ander register	METC : 2012/259
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A