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A prospective randomised controlled trial assessing the efficacy of Pegatanib sodium (Macugen®) in the prevention of proliferative diabetic retinopathy

Submission date 29/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/04/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/07/2016	**Condition category** Eye Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Narinder Sangha

Contact details
Frimley Park Hospital
Maple House
Surrey
United Kingdom
GU16 7UJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
6648

Study information

Scientific Title
A prospective randomised controlled trial assessing the efficacy of Pegatanib sodium (Macugen®) in the prevention of proliferative diabetic retinopathy

Acronym
Macugen®

Study objectives
Multi-centre prospective randomised controlled study to assess the efficacy of intravitreal Macugen® injections to prevent the development of proliferative diabetic retinopathy (early treatment diabetic retinopathy study [ETDRS] = 61) compared to standard care (no treatment) in patients with severe non-proliferative diabetic retinopathy (sNPDR) (ETDRS = 53 A - E).

The objective of the study is to assess whether Macugen® given at these time points of diabetic retinopathy can prevent the conversion to sight threatening PDR.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 08/H1102/91)

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Eye; Subtopic: Eye (all Subtopics); Disease: Ophthalmology

Interventions
90 subjects with ETDRS 53 A - E will be enrolled into the study. Baseline examination will include of best-corrected visual acuity (BCVA), fundus examination, 7-field retina colours and fundus fluorescein angiography with peripheral sweeps. The patients in the treatment arm will have 3 injections of intravitreal Macugen® 0.3 mg at baseline, 6 weeks and 12 weeks. All patients will be followed up at 12 weekly intervals.

Treatment group: baseline, week 6, 12, 24, 36, 48, 60, 72, 84, 96 and 108 weeks
Control arm: baseline, 12, 24, 36, 48, 60, 72, 84, 96 and 108 weeks

Follow up investigation include BCVA, fundus examination and 7-field retinal colour photographs at every visit. FFA with peripheral sweeps will be done at 12, 36, 60, 84 and 108 weeks follow-up. Pan retinal photocoagulation (PRP) will be carried out at any visit if the level of retinopathy progresses to ETDRS = 61. Subjects will be evaluated for ocular and systemic adverse events at all visits and any unscheduled visits.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Pegatanib sodium (Macugen®)

Primary outcome measure
The proportion of eyes that progress to ETDRS = 61 following three injections of intravitreal Macugen®

Secondary outcome measures
1. The mean change in size of foveal avascular zone (FAZ) from baseline to end of 12 months and 24 months
2. The rate (timepoint) of development of neovascularisation
3. Rates of ocular and non-ocular adverse events
4. The visual outcome in the study eye will be compared to control eyes

Overall study start date
01/01/2009

Completion date
01/01/2011

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Planned Sample Size: 90

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2009

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Frimley Park Hospital
Surrey
United Kingdom
GU16 7UJ

Sponsor information

Organisation
Frimley Park Hospital NHS Foundation Trust (UK)

Sponsor details
Maple House
Portsmouth Road
Frimley
Surrey
England
United Kingdom
GU16 7UJ

Sponsor type
Hospital/treatment centre

Website
http://www.frimleypark.nhs.uk/

ROR
https://ror.org/00mrq3p58

Funder(s)

Funder type
Industry

Funder Name
Pfizer (UK)

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No