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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

**Registration date**
29/04/2010

**Overall study status**
Completed

**Last Edited**
14/07/2016

**Condition category**
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
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)

## Primary study design
Interventional

## Study design
Randomised interventional treatment trial

## Study type(s)
Treatment

## 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(s)
The proportion of eyes that progress to ETDRS = 61 following three injections of intravitreal Macugen®

### Key secondary outcome(s)
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

### Completion date
01/01/2011

## Eligibility

### Key inclusion criteria
Not provided at time of registration

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex

### 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

United Kingdom

England

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

# Sponsor information

**Organisation**
Frimley Park Hospital NHS Foundation Trust (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, Pfizer Inc

**Funding Body Type**
Government organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
United States of America

# Results and Publications

# Individual participant data (IPD) sharing plan

## IPD sharing plan summary

## Study outputs

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