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A trial of intraoperative 5-fluorouracil (5-FU) in primary glaucoma surgery: effects on long term intraocular pressure control and disease progression

Submission date
24/10/2000

Recruitment status
No longer recruiting

Registration date
24/10/2000

Overall study status
Completed

Last Edited
12/02/2018

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
G9330070

Study information

Scientific Title
A trial of intraoperative 5-fluorouracil (5-FU) in primary glaucoma surgery: effects on long term intraocular pressure control and disease progression

Study objectives
The aim of this study is to determine in a prospective, randomised, double masked study if a single intraoperative exposure to 5-FU during glaucoma filtration surgery versus a placebo treatment results in statistically and clinically significant long term differences at various time intervals in the following parameters:
1. Visual function as measured with computerised visual fields testing with multiple point regression analysis
2. Optic disc cupping measured with conventional photographic imaging and three dimensional analysis using the Laser Scanner Ophthalmoscope
3. Intraocular pressure defined as the percentage of patients in each group who have pressure under 21, 17 and 15 off medication
4. Incidence of short and long term surgical complications.
A second purpose of this study is to research in detail the normal long term surgical outcome, complication rate, visual function and optic disc change following glaucoma filtration surgery, particularly the relationship with the level of intraocular pressure

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Glaucoma

Interventions
5-FU versus placebo

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
5-fluorouracil

Primary outcome(s)

Levels of intraocular pressure following surgery

Key secondary outcome(s)
Changes in visual fields and optic disc cupping

Completion date
20/11/2003

Eligibility

Key inclusion criteria
Patients who are deemed to have inadequate intraocular pressure control in one or both eyes with or without medical treatment, who are listed for glaucoma filtration surgery by their consultant

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Anterior segment percutaneous versus aphakia
2. Previous glaucoma filtration surgery
3. Uveitis
4. Any previous intraocular surgery

Date of first enrolment
01/09/1995

Date of final enrolment
20/11/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Moorfields Eye Hospital and Institute of Ophthalmology
London
United Kingdom
EC1V 9EL

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration