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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	[_] Prospectively registered [_] Protocol
Registration date 24/10/2000	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/02/2018	**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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Levels of intraocular pressure following surgery

Secondary outcome measures
Changes in visual fields and optic disc cupping

Overall study start date
01/09/1995

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
367

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
England

United Kingdom

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

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
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Sponsor type
Research council

Website
http://www.mrc.ac.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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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