

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/02/2018	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr PT Khaw

Contact details

Moorfields Eye Hospital and Institute of Ophthalmology

Bath Street

London

United Kingdom

EC1V 9EL

+44 (0)20 7608 6887

p.khaw@ucl.ac.uk

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

20 Park Crescent

London

United Kingdom

W1B 1AL

+44 (0)20 7636 5422

clinical.trial@headoffice.mrc.ac.uk

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