

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

<b>Submission date</b> 24/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 24/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/02/2018	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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### Contact details

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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

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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