

# Radiotherapy in the treatment of subfoveal neovascular membranes (CNVM) in age-related macular degeneration (ARMD) of the eye: a randomised controlled trial

<b>Submission date</b> 17/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/03/2009	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Professor Usha Chakravarthy

**Contact details**  
Department of Ophthalmology  
Queen's University of Belfast  
Royal Victoria Hospital  
Belfast  
United Kingdom  
BT12 6BA

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

## Acronym

SFRADS

## Study objectives

To determine if radiotherapy has a treatment benefit in CNVM at a total dose of 12 Gy. To monitor for any adverse side-effects attributable to radiotherapy. To assess quality of life improvements attributable to therapy using a package of instruments which will be validated during the course of the study. To carry out an economic assessment by establishing the cost of treatment and any offsetting savings to the health and personal; social services associated with treatment.

## 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)

Not specified

## Study type(s)

Treatment

## Participant information sheet

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

Subfoveal neovascular membranes

## Interventions

Radiotherapy at a total dose of 12 Gy versus control

## Intervention Type

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Efficacy: distance visual acuity (ETDRS), near visual acuity (ETDRS), contrast sensitivity (Pelli Robson), reading speed, ophthalmoscopy, slit-lamp biomicroscopy, fundus photography, fluorescein angiography, generic quality of life questionnaire, condition-specific quality of life questionnaire, assessment of tear film, lens clarity, retinal vasculature and (electrophysiology to monitor retinal and optic nerve function [Belfast only])
2. Health economics: evaluation of treatment costs, care costs, costs on patient and family

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/12/1995

**Completion date**

01/12/1998

**Eligibility****Key inclusion criteria**

Target population aged 60 years or over, with subfoveal CNVM and diagnosis of ARMD confirmed by the clinical and angiographic examination

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Both

**Target number of participants**

240

**Key exclusion criteria**

1. Patients under 60 years of age
2. Those with vision worse than Bailey Lovie 1.0
3. Patients not wishing to be included in the study
4. Patients with unstable hypertension, diabetes or generalised vasculitides and or life-threatening disorder making three year survival unlikely.

**Date of first enrolment**

01/12/1995

**Date of final enrolment**

01/12/1998

# Locations

## Countries of recruitment

Northern Ireland

United Kingdom

## Study participating centre

Department of Ophthalmology

Belfast

United Kingdom

BT12 6BA

# Sponsor information

## Organisation

Medical Research Council (UK)

## Sponsor details

20 Park Crescent

London

United Kingdom

W1B 1AL

+44 (0)20 7636 5422

[clinical.trial@headoffice.mrc.ac.uk](mailto: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 (UK) (ref: G9404235)

## 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

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/08/2002		Yes	No
<a href="#">Results article</a>	results	01/08/2005		Yes	No