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

Submission date
17/10/2000

Recruitment status
No longer recruiting

Registration date
17/10/2000

Overall study status
Completed

Last Edited
26/03/2009

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
MRC ref: G9404235

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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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
United Kingdom

Northern Ireland

Study participating centre
Department of Ophthalmology
Belfast
United Kingdom
BT12 6BA

Sponsor information

Organisation
Medical Research Council (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

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?
Results article	results	01/08/2002		Yes	No
Results article	results	01/08/2005		Yes	No