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Lumbar spine radiology in primary health care: clinical outcomes and cost-effectiveness

Submission date	Recruitment status	[ ] Prospectively registered
25/04/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/04/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/12/2019	Musculoskeletal Diseases	[ ] 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
HTA 93/17/22

Study information

Scientific Title
Lumbar spine radiology in primary health care: clinical outcomes and cost-effectiveness

Study objectives
We propose to conduct a randomised controlled trial (RCT) of lumbar spine radiology in primary health care focused on general practices and their local hospital radiology departments in the former Northern and Yorkshire region of the NHS. 1,300 patients will be randomised as follows:
Group 1 - no hospital radiology referral (400)
Group 2 - simulated (placebo) X-ray procedure (300)
Group 3 - lumbar spine radiology (600)
The study will ensure that a comparison of 600 patients receiving lumbar spine radiology with 700 patients acting as controls has a 95% power to detect a 0.25 sd difference at the 1% level on the Aberdeen scale.

Please note that, as of 11/05/2009, the anticipated end date has been updated from 30/04/1999 to 30/05/1999.

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal diseases: Spinal conditions

Interventions
Group 1 - no hospital radiology referral (400)
Group 2 - simulated (placebo) X-ray procedure (300)
Group 3 - lumbar spine radiology (600)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. General health profile (SF36)
2. Condition specific questionnaire for low back pain (Aberdeen scale)
3. Quality of life instrument (Euroquol)
4. Treatments given
5. Referrals made
6. Numbers of consultations
7. Numbers, lengths and costs of certified absences from work
8. Radiological reports

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/10/1996

Completion date
30/05/1999

Eligibility

Key inclusion criteria
Not provided at time of registration.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
1300

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/10/1996

Date of final enrolment
30/05/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
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+44 (0)1132 545 843
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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