

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

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| Submission date 25/04/2003 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 25/04/2003 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 12/12/2019 | Condition category Musculoskeletal 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

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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 (Euroqol)
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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Leeds

United Kingdom

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Sheila.Greener@doh.gsi.gov.uk

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