

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

Submission date 25/04/2003	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 25/04/2003	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 12/12/2019	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr JP Owen

Contact details
Queen Victoria Road
Royal Victoria Infirmary
Newcastle upon Tyne
United Kingdom
NE1 4LP
+44 (0)191 282 4256
j.y.stoddart@ncl.ac.uk

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration.

Completion date

30/05/1999

Eligibility

Key inclusion criteria

Not provided at time of registration.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Queen Victoria Road

Newcastle upon Tyne

United Kingdom

NE1 4LP

Sponsor information

Organisation

Department of Health (UK)

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration