

A randomised controlled trial to assess the effectiveness, cost-effectiveness and cost benefit of routine referral for lumbar spine radiography in patients with low back pain

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| Submission date 25/04/2003 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 25/04/2003 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 06/02/2019 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Denise Kendrick

ORCID ID

<https://orcid.org/0000-0003-3603-6542>

Contact details

Division of General Practice

University of Nottingham

Floor 13

Tower Building

University Park

Nottingham

United Kingdom

NG7 2RD

+44 0115 8466914

denise.kendrick@nottingham.ac.uk

Additional identifiers

Protocol serial number

HTA 93/17/13

Study information

Scientific Title

A randomised controlled trial to assess the effectiveness, cost-effectiveness and cost benefit of routine referral for lumbar spine radiography in patients with low back pain

Study objectives

To test the hypotheses that:

1. Lumbar spine radiography in primary care patients with low back pain is not associated with improved patient outcomes, including pain, disability, health status, sickness absence, reassurance, and patient satisfaction or belief in the value of radiography.
2. Lumbar spine radiography in primary care patients with low back pain is not associated with changes in patient management, including medication use, and the use of primary and secondary care services, physical therapies and complementary therapies.
3. Participants choosing their treatment group (i.e. radiography or no radiography) do not have better outcomes than those randomised to a treatment group.
4. Lumbar spine radiography is not cost-effective compared with usual care without lumbar spine radiography.

Please note that, as of 16 January 2008, the end date of this trial has been updated from 31 December 1999 to 31 March 2000.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Current ethics approval as of 06/02/2019:

Queens Medical Centre, University Hospital, NHS Trust Ethics Committee, 03/04/1995.

Nottingham City Hospital Ethics Committee, 31/03/1995, ref. EC95/69.

Southern Derbyshire Ethics Committee, 19/09/1995, ref. 95/08/71.

North Lincolnshire Research Ethics Committee, 23/11/1995, ref. BBS/EAH/106.

North Nottinghamshire Health Authority, 03/04/1995, ref. NNHA/171.

Leicestershire Health Authority, 07/02/1997, ref. 4521.

Previous ethics approval:

Queens Medical Centre, Nottingham

Southern Derbyshire's ethics committee

North Lincolnshire's research ethics committee

North Nottinghamshire health authority

Leicestershire health authority

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Musculoskeletal diseases: Spinal conditions

Interventions

Lumbar spine radiography and usual care versus usual care without radiography.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Roland adaptation of the Sickness Impact Profile, visual analogue pain scale, health status scale, EuroQol, use of primary and secondary care services, and physical and complementary therapies, sickness absence, medication use, patient satisfaction, reassurance and belief in value of radiography at 3 and 9 months post-randomisation.

Key secondary outcome(s)

Not provided at time of registration.

Completion date

31/03/2000

Eligibility

Key inclusion criteria

Seventy-three general practices in Nottingham, North Nottinghamshire, Southern Derbyshire, North Lincolnshire and North Leicestershire. Fifty-two practices recruited participants to the trial.

Randomised arm: 421 participants with low back pain, with median duration of 10 weeks.

Patient preference arm: 55 participants with low back pain, with median duration of 11 weeks

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/07/1995

Date of final enrolment

31/03/2000

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Division of General Practice

Nottingham

United Kingdom

NG7 2RD

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/02/2001 | | Yes | No |
| Results article | results | 17/02/2001 | | Yes | No |
| Results article | results | 15/10/2002 | | Yes | No |