

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

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

<http://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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Not Specified

Participant information sheet

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 measure

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.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

01/07/1995

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

Age group

Not Specified

Sex

Both

Target number of participants

476

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

England

United Kingdom

Study participating centre

Division of General Practice

Nottingham

United Kingdom

NG7 2RD

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House
Quarry Hill
Leeds
United Kingdom
LS2 7UE
+44 (0)1132 545 843
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

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

