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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

Registration date
25/04/2003

Overall study status
Completed

Last Edited
06/02/2019

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 93/17/13

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

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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

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