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Diagnostic accuracy of the Thessaly test, the standardised clinical history, and other clinical examination tests for meniscal tears

Submission date
08/11/2012

Recruitment status
No longer recruiting

Registration date
12/11/2012

Overall study status
Completed

Last Edited
05/05/2016

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
The menisci are two discs located in each knee. They play an important role in the function of the knee, providing load bearing, stress distribution and shock absorption across the knee. Tears in the menisci are a common knee injury that can cause pain in the joint. However, reliable non-invasive diagnosis of meniscal tears is difficult. There are a number of physical examination tests described that diagnose tears but all suffer from a lack of specificity and sensitivity, that is they sometimes diagnose tears where one does not exist or fail to diagnose tears when they do exist. The Thessaly test is a new clinical examination used to detect meniscal tears in the knee and is claimed to have high sensitivity and specificity. It may be suitable as an inexpensive diagnostic tool to differenciate patients who do and do not require to be referred on to hospital for expensive MRI scans and arthroscopy (is keyhole surgery that is used to diagnose joint problems and repair joint damage) which will save large sums of money for the NHS as well as preventing unnecessary additional procedures for patients.

Who can participate?
The study will recruit two groups of patients, one group with knee pain and on group without knee pain.

What does the study involve?
Patients recruited to the study who have existing knee pain will follow standard assessment pathways. This will involve assessment by an experienced musculoskeletal clinician followed by an X-Ray and MRI scan of the knee. The only additional procedure for this group of knee patients will be a subsequent knee examination by a primary healthcare professional (GP or physiotherapist). The second group of patients with no knee pain (control patients) will also be asked to undergo physical knee examination by an experienced musculoskeletal clinician and a a primary healthcare professional (GP or physiotherapist) followed by an MRI scan of the knee.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in this study. However, by participating the diagnostic accuracy of the Thessaly tests can be determined and whether it is a good alternative to MRI

scans and arthroscopy to determine meniscal tears. If the Thessaly test, or any combination of tests used during this study, are good at diagnosing meniscal tears they could be used by primary healthcare professionals (GP and physiotherapist) and prevent people without meniscal tears going to hospital for MRI scans and knee arthroscopy. This could also free up additonal NHS resources. There are no risks in taking part in this study. The only disadvantage is that the clinic appiointments will take slightly longer as additional physical examinations of the knee will be carried out. For those patients recruited to the control group there will also be an additional hospital visit for an MRI scan of the knee.

Where is the study run from?
The study is being run at Glasgow Royal Infirmary Orthopaedic department.

When is the study starting and how long is it expected to run for?
The study will commence in December 2012 and will recruit patients for approximately 9 months.

Who is funding the study?
The study is funded by the National Institute for Health Research - Health Technology Assessment Programme.

Who is the main contact?
Dr Katriona Brooksbank, Research Manager
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 09/163/02

Study information

Scientific Title
Diagnostic accuracy of the Thessaly test, the standardised clinical history, and other clinical examination tests for meniscal tears

Study objectives
1. To determine the diagnostic accuracy of the Thessaly test by GPs for meniscal tear in the knee and whether this test can obviate the need for further investigation by arthroscopy or magnetic resonance imaging (MRI).
2. To determine how the Thessaly test compares to clinical history and other commonly used physical examinations (McMurray test, Apleys test, joint line tenderness test) in diagnosing meniscal tears by GPs.
3. To determine if the presence of arthritis or other knee pathologies influences the accuracy of the Thessaly.
4. To determine if the use of combinations of physical tests (such as the Thessaly test, McMurray test, Apleys test and or joint line tenderness test) by GPs provides better specificity and sensitivity than a single test alone in the diagnosis of meniscal tear.
5. To determine the ability of non-specialist General Practitioners to use the Thessaly test in comparison to specialist knee clinicians.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0916302

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Service, 16/10/2012, ref: 12/WS/0225

Study design
Single-centre randomised controlled trial
Methodology: Case-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Meniscal tear in knees

Interventions
We do not plan to make any direct interventions in either of our patient groups. We will merely make assessments of patients knees (both healthy and knee patients) using physical examinations, X-ray and MRI scans (however X-rays will only be on the knee patients).

The randomisation in the study is with regard to the order of physical examination tests. The methodology for this study is case control.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Sensitivity and specificity of the Thessaly test, in determining the presence of meniscal tears, when employed by General Practitioners.

Secondary outcome measures
1. Sensitivity and specificity of the Thessaly test, in determining the presence of meniscal tears, when employed by specialist knee clinicians.
2. Sensitivity and specificity of the McMurray test, Apley test, joint line tenderness test and clinical history in determining the presence of meniscal tears.
3. Determination of the influence of osteoarthritis on the sensitivity and specificity of the Thessaly test, McMurray test, Apley test and joint line tenderness test.
4. Determine of the influence of other knee pathology such as ACL (anterior cruciate ligament) damage on the sensitivity and specificity of the Thessaly test, McMurray test, Apley test and joint line tenderness test.
5. Determination of the optimal combination of physical tests for most accurate diagnosis of meniscal tear in a primary care setting.

Overall study start date
28/11/2012

Completion date
05/05/2014

Eligibility

Key inclusion criteria
Knee patients referred to knee clinic at Glasgow Royal Infirmary
Control patients - attending hand clinic at Glasgow Royal Infirmary

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Knee patients = 300, control patients = 50

Key exclusion criteria
Knee patients
1. Age under 18 years
2. Unable to give informed consent
3. Previous knee replacement on referred knee

Control patients
1. Age under 18 years
2. Unable to give informed consent
3. Previous knee replacement on referred knee
4. History of knee pain (last 6 months)
5. Osteoarthritis
6. Rheumatoid arthritis

Date of first enrolment
28/11/2012

Date of final enrolment
05/05/2014

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Glasgow Royal Infirmary
Glasgow
United Kingdom
G4 0SF

Sponsor information

Organisation
National Institute for Health Research (UK)

Sponsor details

University of Southampton
Alpha House, Enterprise Road
Southampton
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Sponsor type
Government

Website
http://www.netscc.ac.uk

ROR
https://ror.org/0187kwz08

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/08/2015		Yes	No