

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

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Registration date 12/11/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/05/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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 differentiate 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 one 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 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 additional NHS resources. There are no risks in taking part in this study. The only disadvantage is that the clinic appointments 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

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Scotland

Study participating centre

Glasgow Royal Infirmary

Glasgow

United Kingdom

G4 0SF

Sponsor information

Organisation

National Institute for Health Research (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, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2015		Yes	No