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

Submission date	Recruitment status	[X] F
08/11/2012	No longer recruiting	[] P
Registration date	Overall study status	[] S
12/11/2012	Completed	[X] F
Last Edited 05/05/2016	<b>Condition category</b> Musculoskeletal Diseases	[] Ir

[X] Prospectively registered

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- ] 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 katriona.brooksbank@ggc.scot.nhs.uk

## **Contact information**

**Type(s)** Scientific

**Contact name** Mr Mark Blyth

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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 United Kingdom SO16 7NS

**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