

Temporal artery biopsy vs ultrasound in diagnosis of giant cell arteritis

Submission date 18/10/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/11/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/06/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Giant Cell Arteritis (GCA) causes inflammation and narrowing of blood vessels and can cause blindness in one third of patients. It is important that GCA is identified promptly and accurately and treated for two or more years. Currently there is no test that is 100% accurate at identifying GCA. Patients usually have new headache and scalp tenderness, typically with an abnormal blood test. However, it can be difficult to distinguish between non-serious forms of headache and GCA. Infection produces similar abnormal blood results. If there is a suspicion of GCA, treatment with steroids is started straight away. To confirm a diagnosis, a sample is taken from the blood vessel in the scalp (biopsy). This is called TAB (temporal artery biopsy). However, up to 44% of patients will show normal results in the biopsy. Therefore it is difficult to know if a patient with a normal biopsy does or does not have GCA. Stopping steroid treatment may increase the risk of blindness. Continuing treatment in a patient without GCA increases the risk of side effects. It is important to improve diagnostic tests for GCA. Another test that helps in diagnosing GCA is an ultrasound scan of the arteries on the side of the head and under the arms. Ultrasound does not involve surgery; it is a simple test which can be performed as an out-patient. In this study we aim to find out the effectiveness of the ultrasound scan.

Who can participate?

Participants with new suspicion of GCA can take part in this study.

What does the study involve?

At their first visit, all patients have initial tests like blood tests, ultrasound examination and a temporal artery biopsy (TAB) within 7 days of starting high-dose steroid treatment. Participants are treated according to usual practice and followed up as part of the study at two weeks (Visit 2) and six months (Visit 3). After six months, the accuracy of ultrasound is assessed compared with or combined with biopsy. The study also looks at whether a doctor's knowledge of the ultrasound results or the biopsy results alone, or knowledge of both results together, would affect the diagnosis and recommendation to continue or stop steroid treatment.

What are the possible benefits and risks of participating?

The potential benefit is the ability to continue or withdraw steroid treatment appropriately (rather than promptly start the treatment) on the basis of a more accurate diagnosis. If the

patient has a negative biopsy but a very positive ultrasound scan, there is the possibility that the patient would have treatment withdrawn. Participants benefit from having a non-invasive ultrasound as opposed to an invasive biopsy. This can lead to discontinuation of steroid treatment and improve quality of life. There are three possible risks. There is a possibility of delay in performing a biopsy within 7 days of starting steroid treatment. This should not be an issue as a delay in getting the ultrasound scan done is not expected. There is the possibility of withdrawing the steroid treatment in a biopsy-negative participant where the ultrasound indicates strong evidence of GCA. If the participant's doctor has ruled out GCA and is planning to withdraw steroid treatment, they must contact the trialists for the ultrasound result. It is also possible that a doctor may diagnose GCA at Visit 2 (two weeks) and continue steroid treatment, but may subsequently consider withdrawing steroids due to the possibility of an incorrect diagnosis and potential safety issues relating to steroid toxicity. In these circumstances the doctor can request the ultrasound result.

Where is the study run from?

21 hospitals across the UK (Oxford, Aylesbury, Nottingham, Westcliff-on-Sea, Romford, Portsmouth, Birmingham, Derby, Leeds, Sunderland, Dudley, Reading, Gateshead, Great Yarmouth, Harlow, Belfast), Ireland (Dublin), Norway (Kristiansand), Germany (Jena) and Portugal (Lisbon). The lead centre is the Nuffield Orthopaedic Centre, Oxford (UK).

When is study starting and how long is it expected to run for?

June 2010 to December 2014

Who is funding the study?

Health Technology Assessment Programme (UK)

Who is the main contact?

Prof. Raashid Luqmani

tabul@ndorms.ox.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Raashid Luqmani

Contact details

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Science (NDORMS)

University of Oxford

Rheumatology Department

Nuffield Orthopaedic Centre

Windmill Road

Oxford

United Kingdom

OX3 7LD

+44 (0)1865 227971

raashid.luqmani@ndorms.ox.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)

NCT00974883

Protocol serial number

HTA 08/64/01

Study information

Scientific Title

The role of ultrasound compared to biopsy of temporal arteries in the diagnosis and treatment of Giant Cell Arteritis (GCA)

Acronym

TABUL

Study objectives

In this study the value of ultrasound examination of temporal arteries as an adjunct to diagnosis of GCA will be assessed in addition to its potential role as a substitute for temporal artery biopsy. Ultrasound examination of temporal arteries is non invasive and does not involve ionizing radiation. It can provide information about the vessel wall throughout the length of the vessel and potentially can evaluate the presence of skip lesions which are a significant problem in histological examination.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Berkshire Research Ethics Committee, 14/01/2010, ref: 09/H0505/132

TABUL Amendment 1 Approval 29/03/2011

TABUL Amendment 2 Approval 11/03/2013

Study design

Prospective cohort study using a paired design, i.e. all participants will have both ultrasound and temporal artery biopsy (TAB)

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Giant Cell Arteritis (GCA)

Interventions

All participants will have both ultrasound and temporal artery biopsy (TAB).

For the ultrasound, scans will be performed of the temporal and axillary arteries on both sides using high resolution ultrasound equipment to detect halo, stenosis or occlusion.

For the temporal artery biopsy (TAB) - a biopsy of the temporal artery from the symptomatic side.

The ultrasound scan will be carried out before the TAB and both procedures will be performed within 7 days of starting high-dose glucocorticoids. After the initial consultation at baseline (Visit 1), participants will be followed up at two weeks (Visit 2) and six months (Visit 3).

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. To evaluate the diagnostic accuracy (sensitivity and specificity) of ultrasound as an alternative to temporal artery biopsy for the diagnosis of GCA in patients referred for biopsy with suspected GCA (method: ultrasound scan and TAB, time point: six months)
2. To evaluate the cost-effectiveness (incremental cost per QALY) of ultrasound instead of biopsy in the diagnosis of GCA (time point: six months)

Key secondary outcome(s)

1. To evaluate inter-observer agreement in the assessment of ultrasound and temporal artery biopsy (time frame: six months)
2. To elicit expert views on the appropriateness of performing a biopsy following ultrasound using clinical vignettes (time frame: three years)
3. To evaluate the diagnostic accuracy (sensitivity and specificity) of the sequential diagnostic strategy from 4 as an alternative to temporal artery biopsy alone in the diagnosis of GCA (time frame: three years)
4. To evaluate the cost-effectiveness (incremental cost per QALY) of the diagnostic strategy from 4 instead of biopsy alone in the diagnosis of GCA (time frame: three years)

Completion date

31/12/2014

Eligibility

Key inclusion criteria

For the cohort study:

1. A clinical suspicion of new diagnosis of GCA e.g. patients with a new onset of headache, scalp tenderness, with or without elevated C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR), jaw or tongue claudication with or without visual loss
2. The clinician decides that the patient requires an urgent temporal artery biopsy to determine whether or not the diagnosis is GCA
3. The patient agrees and provides consent to undergo a temporal artery biopsy as part of standard care
4. Patients have been started on high-dose glucocorticoids or will be started on high-dose glucocorticoids
5. Patients must be willing to attend for an ultrasound scan of their temporal and axillary arteries
6. Participants must be willing to give informed written consent or willing to give permission for a nominated friend or relative to provide written informed assent if they are unable to do so because of physical disabilities e.g. sudden onset of blindness/vision loss which can be caused by

GCA (this will be made clear in the ethics approval application)

7. Must be 18 years of age or over

For the training cases:

1. Patients attending hospital outpatient or inpatient departments for assessment for any condition (apart from giant cell arteritis or polymyalgia rheumatica) or healthy staff volunteers
2. Above the age of 50 years
3. Willing to attend for an ultrasound scan of their temporal and axillary arteries
4. Willing and able to give written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

For the cohort study:

1. Previous diagnosis of GCA
2. Use of high-dose glucocorticoid (>20 mg prednisolone/day) for management of current suspected GCA for more than 7 days prior to the dates of the ultrasound and biopsy
3. Long-term (>1 month) high-dose (>20 mg per day at any time) steroids for conditions other than polymyalgia rheumatica (PMR), within three months prior to study entry
4. Inability to give informed consent (either written consent or verbal assent from a relative or carer)
5. Inability to undergo an ultrasound scans of the temporal and axillary arteries
6. Patients with a known cause of headache (not due to GCA), or any condition which would preclude the need for a temporal artery biopsy
7. Patients who are unable to undergo an ultrasound scan and a temporal artery biopsy within 7 days of starting glucocorticoids

For the training cases:

1. Diagnosis of suspected GCA or a previous history of diagnosed or suspected GCA
2. Inability to give written informed consent
3. Inability to undergo an ultrasound scan of the temporal and axillary arteries

Date of first enrolment

01/06/2010

Date of final enrolment

01/12/2013

Locations

Countries of recruitment

United Kingdom

England

Germany

Ireland

Norway

Portugal

Study participating centre

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Science (NDORMS)

Oxford

United Kingdom

OX3 7LD

Sponsor information

Organisation

University of Oxford (UK)

ROR

<https://ror.org/052gg0110>

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	01/11/2016		Yes	No
Results article	results	29/03/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes