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Adalimumab in low back pain

Submission date 01/09/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 21/09/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 29/05/2020	**Condition category** Signs and Symptoms	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Lower back pain is a common problem, which affects most people at some point in their lives. Many people who experience LBP will recover quickly with no significant impact to their lives, but for some people the pain turns into a long term condition which can affect their ability to work. When a sufferer experiences episodes which last for at least three months, it is known as chronic lower back pain (CLBP). For some patients, their CLBP is caused by inflammation (swelling) in the vertebrae (small bones which make up the spite). Adalimumab is a medication used in patients with inflammatory conditions such as arthritis, as it works by reducing inflammation. The aim of this study is to investigate the effectiveness of treating patients who have CLBP caused by inflammation with adalimumab.

Who can participate?
Adults with CLBP which is caused by inflammation.

What does the study involve?
All participants receive a subcutaneous injection (injection under the skin) of 40mg Adalimumab every other week for 12 weeks. During this time, and for two weeks after the end of treatment, participants are askedto keep a record of any pain medication they take, which is reviewed at the start of the study, each time they have an injection and two weeks after the end of treatment. At the start of the study and then after 12 weeks, participants complete a number of questionnaires to assess their pain levels and disability. In addition, participants also have an MRI scan at the start of the study and after 12 weeks to measure the swelling (inflammation) in their spine).

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in pain and disability. There is a small risk that participants may be more vulnerable to developing an infection while taking the study drug.

Where is the study run from?
1. University Hospital of Geneva (Switzerland)
2. HFR- Fribourg Cantonal Hospital (Switzerland)

When is the study starting and how long is it expected to run for?
July 2010 to January 2015

Who is funding the study?
1. University Hospital of Geneva (Switzerland)
2. AbbVie (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CE 10 139

Study information

Scientific Title
Anti-TNF treatment in patients with chronic low back pain associated with Modic I changes: An exploratory trial

Study objectives
Adalimumab could be a potentiel treatment for low back pain patient with Modic I endplate changes.

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Ethical committee of Geneva University Hospital, 09/11/2011, ref: 10-139
2. Swissmedic, 16/12/2011, ref: 2011DR2213

Study design
Pilot one-arm non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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
Chronic low back pain patient with inflammatory pain pattern and Modic I endplate changes

Interventions
All patients receive a subcutaneous injection of Adalimumab 40mg every other week for 12 weeks.

Participants are asked to keep a pain medication diary from baseline until 2 weeks after the intervention, which is reviewed at baseline and then every 2 weeks until the final follow up 2 weeks after the intervention ends. Participants complete follow up questionnaires and undergo MRI scanning at 12 weeks.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Adalimumab (Humira)

Primary outcome measure
Pain is measured using a numerical rating scale (NRS) and the Roland Disability Questionnaire (RDQ) at baseline and 12 weeks.

Secondary outcome measures
1. Morning stiffness is measured using a numerical rating scale (NRS) at baseline and 12 weeks
2. Quality of sleep is measured using a numerical rating scale (NRS) at baseline and 12 weeks
3. Patient Global Improvement is measured using a numerical rating scale (NRS) at baseline and 12 weeks
4. Function is measured using Bath Ankylosing Spondilitis disease activity index (BASDAI) at baseline and 12 weeks
5. Health related quality of life is measured using the EuroQol-5 dimensions (EQ-5D) at baseline and 12 weeks
6. Pain medication taken is measured using the Pain Medication Diary at baseline and then every 2 weeks until 2 weeks post-intervention
7. Duration of sick listing is measured by questionnaire at baseline and 2 weeks post-intervention
8. Size of bone oedema is measured using MRI (Modic I) at baseline and 12 weeks

Overall study start date
07/07/2010

Completion date
23/01/2015

Eligibility

Key inclusion criteria
1. Age 18-65 years
2. Signed Informed Consent
3. Common low back pain
4. The presence of 2 out of 3 of the following points, indicating inflammatory back pain:
4.1. Insidious onset
4.2. Morning stiffness
4.3. Improvement with exercise
5. Continuous pain for more than 3 months
6. Failure of at least one full course of non steroidal anti-inflammatory drug
7. Pain > 3/10 on a 0 to 10 numeric rating scale over the last 24 hours
8. At least one Modic I modification on lumbar MRI

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
25

Key exclusion criteria
1. A diagnosis of spondylarthropathy following standard definition
2. Either : Presence of sacroiliitis on imaging
or At least 2 of the following
Inflammatory Bowel Disease, Arthritis, Enthesitis, Dactylitis, Uveitis, Psoriasis, Family history of spondylarthropathy, Elevated CRP or sedimentation rate
3. Radicular pain related to disc herniation
4. Neurogenic claudication related to lumbar stenosis
5. Comorbidities impairing with the evaluation of pain or function
6. Concomitant infection
6.1. In case of tuberculosis (positive TBspot) at least one month of antituberculosis treatment is required before considering inclusion
6.2. Active Hepatitis B infection (screening for active HBV infection will be performed)
7. Women of child-bearing age refusing to use contraceptive measure during the study, Pregnancy (pregnancy test will be performed before inclusion), breastfeeding
8. Heart failure (NYHA III and IV)
9. Current treatment with corticosteroids
10. Prior exposure to anti-TNF agents, including adalimumab
11. Inability to comply with the protocol requirements
12. Past history of cancer
13. Demyelinating diseases
14. Allergy to adalimumab or one of its components
15. Unable to read and understand the questionnaires (in French)
16. Poor motivation or other emotional or intellectual problems that are likely to limit the ability of the patient to comply with the protocol requirements

Date of first enrolment
02/06/2013

Date of final enrolment
24/10/2014

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital of Geneva
Division of Rheumatology
Geneva
Switzerland
1211

Study participating centre
HFR- Fribourg Cantonal Hospital
Department of Rheumatology, Physical Medicine and Rehabilitation
Fribourg
Switzerland
1708

Sponsor information

Organisation
University Hospital of Geneva

Sponsor details
Perret-Gentil 4
Geneva
Switzerland
1211

Sponsor type
Hospital/treatment centre

Website
http://www.hug-ge.ch/

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of Geneva

Funder Name
AbbVie

Alternative Name(s)
AbbVie Inc., AbbVie U.S., AbbVie US, Allergan

Funding Body Type

Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Results will be presented in rheumatology and back pain congress. They will then be published in peer-reviewed journals.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request