PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Prospective multicenter Study to evaluate the Effect of tight and systematic monitoring by Ultrasound on Therapy and Outcome in Patients with early rheumatoid Arthritis

Trial Acronym

US Impera Study

URL of the trial

http://nicht vorhanden.

Brief Summary in Lay Language

Musculoskeletal ultrasound (US) examination has become an important technique for monitoring disease activity and therapy response in RA. Its ability to detect early, subclinical soft tissue lesions and superficial bone erosions has made it a valuable tool for daily rheumatologic practice. US is suggested to be more specific and sensitive in detecting synovial inflammation and hypervascularity than clinical assessment due to good soft tissue contrast. Additionally, it is more sensitive than conventional radiography in detecting superficial bone erosions. Therefore, without using this modern imaging, rheumatologists might underestimate severity of disease and might treat inadequately.
Modern ultrasound, including Power Doppler, is considered an ideal bedside tool and "extended diagnostic finger" for the diagnosis and adequate management of RA. Ultrasound machines are widespread in most of the rheumatologic outpatient clinics in Germany. Besides, this method has high patient acceptability.
Backhaus et al. have created a semiquantitative score (German US7 score) which combines soft tissue changes (synovitis, tenosynovitis) and erosive bone lesions in 7 selected joints in one US scoring system. The selected joints give a good reflection of the overall joint inflammatory activity. Also, the concentration on a small number of joints makes it feasible in daily rheumatologic practice.

Brief Summary in Scientific Language

To evaluate the effect of tight and systematic monitoring by musculoskeletal ultrasound on therapy and outcome in Patients with early rheumatoid Arthritis. The improvement in self-report functional status (disability) measured by HAQ after 18 months treatment is measured. To summarize, the objective of this IIT is to explore the impact of systematic use of ultrasound using the US7 based scoring system on both disease activity and functional capacity during the course of rheumatologic treatment, which defines the exploratory character of this study. The statistical method is forward and backward stepwise regression analysis. Subsequent subgrouping will be done according to content-related considerations: Therapy (DMARD vs. bDMARD), Age, Sex, Anti-CCP and RF status, disease activity.

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Organizational Data

- DRKS-ID: **DRKS00010485**
- Date of Registration in DRKS: **2016/06/01**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EA1/051/10 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- Free text: **rheumatoid arthritis**
- ICD10: **M05 - Seropositive rheumatoid arthritis**

Interventions/Observational Groups

- Arm 1: **RA patients who receive an additional US examination by the US7 score to standard clinical care**
- Arm 2: **RA patients who (only) get a clinical examination by standard clinical care.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**

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- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Screening**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Compare functional outcome in patients monitored according to standard care vs. patients additionally monitored by using US7 score. Functional outcome is measured by HAQ.

Secondary Outcome

1. Compare disease activity in patients monitored according to standard care vs. patients additionally monitored by using US7 score.
2. Describe ultrasound driven changes in therapy, e.g. escalation of therapy in dose and regimen
3. Describe change, practicability and costs in patient management and resource allocation in clinic and outpatient clinics related to use of US7 score.
4. How does US7 score influence the therapeutic decisions?
5. Evaluate the clinician’s confidence with regards to his/her decision (on a visual analogue scale) before and after US examination.
6. Define criteria for imaging remission based on functional outcome and disease activity.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Charité Universitätsmedizin Berlin, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/09/06**
- Target Sample Size: **440**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

•Patients, at least 18 years of age, with currently active RA with or without receiving DMARDs. Active disease is defined as DAS 28 > 3.2 and at least swollen joint count (SJC) ≥ 3 and tender joint count (TJC) ≥ 3 included in the 28 joint count.
•Early RA (≤ 2 years from time of onset of arthritic symptoms)

Exclusion criteria

•Patients receiving biologics
•Patients with other chronic inflammatory articular disease or systemic autoimmune disease
•Patients with erosions in conventional radiography taken less than 3 months before start of study
•Patients participating in other studies
•Any active infection, a history of recurrent clinically significant infection, a history of recurrent bacterial infections with encapsulated organisms (known Hepatitis B, C and HIV)
•Primary or secondary immunodeficiency
•History of cancer with curative treatment not longer than 5 years ago except basal-cell carcinoma of the skin that had been excised
•Evidence of significant uncontrolled concomitant diseases or serious and / or uncontrolled diseases that are likely to interfere with the evaluation of the patient's safety and of the study outcome
•Women lactating, pregnant, nursing or of childbearing potential with a positive pregnancy test or planned pregnancy.
•Women of childbearing potential without adequate contraception (medically acceptable methods are contraceptive implant, contraceptive injection, intrauterine device (IUD), or oral contraceptives taken for at least 3 months, which the patient agrees to continue using during the study, or a double-barrier method which must consist of a combination of any of the following: diaphragma, cervical cap, comdom, or spermicide)
•History of alcohol, drug or chemical abuse (defined as impaired / questionable reliability) as well as neurotic personality.
•Neuropathy that can interfere with filling out the patient's questionnaires
•History of a severe psychological illness or condition
•Severe heart failure (New York Heart Association Class III and IV) or severe,

uncontrolled cardiac disease
•Women lactating, pregnant, nursing or child bearing potential with a positive pregnancy test or planned pregnancy.
•Women of childbearing potential without adequate contraception (medically acceptable methods are contraceptive implant, contraceptive injection
•no written consent

Addresses

■ **Primary Sponsor**

Charité Universitätsmedizin Berlin -Med. Klinik mit SP Rheumatologie und Klin. Immunologie
Ms. Prof. Dr. med. Marina Backhaus
Charitéplatz 1
10117 Berlin
Germany

Telephone: **030 450 513 060**
Fax: **030 450 513 939**
E-mail: **marina.backhaus at charite.de**
URL: **[---]***

■ **Contact for Scientific Queries**

Charité Universitätsmedizin Berlin -Med. Klinik mit SP Rheumatologie und Klin. Immunologie
Ms. Dr. med. Sarah Ohrndorf
Charitéplatz 1
10117 Berlin
Germany

Telephone: **030 450 513 060**
Fax: **030 450 513 939**
E-mail: **sarah.ohrndorf at charite.de**
URL: **[---]***

■ **Contact for Public Queries**

Charité Universitätsmedizin Berlin - Med. Klinik mit SP Rheumatologie und Klin. Immunologie
Ms. Gabriela Schmittat
Charitéplatz 1
10117 Berlin
Germany

Telephone: **030 450 513 247**
Fax: **030 450 7513 247**
E-mail: **gabriela.schmittat at charite.de**
URL: **[---]***

Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

  AbbVie Deutschland GmbH & Co. KG
  Mainzer Straße 81
  65189 Wiesbaden
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/02/14**

Trial Publications, Results and other documents

- Abstract **EULAR16-5892-preview**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*