Evaluation of a Standardized Protocol for Dose Reduction in Patients With Spondylarthropathies and Clinical Remission With Anti-TNF Therapy (REDES-TNF/2012)

First published: 04/04/2013

Last updated: 03/09/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/3394

EU PAS number

EUPAS3393

Study ID

3394

DARWIN EU® study

No

Study countries

Spain

Study description

It has been shown that the withdrawal of treatment follows with a flare of the disease in a short time after the suspension but it has not been evaluated in controlled trials if remission could be maintained with a lower dose. A multicenter, national, open-label, randomized and controlled clinical trial of 3 years duration (2 years for inclusion + 1 year follow-up) is proposed to address this issue. The study will include 190 patients with Spondylarthropathies in stable treatment with any single anti-TNF agent and compliance with criteria of clinical remission for at least 4 months. Patients will be randomized to intervention or control arm, with stratification according to the antiTNF product thet were receiving prior to inclusion. Patients will be followed with the calendar of visits recommended by the Spanish Society of Rheumatology for clinical practice. The proposed hypothesis is of non-inferiority of the experimental arm with dose reduction versus the control arm with standard treatment.

Study status

Ongoing

Research institution and networks

Institutions

Consorci Corporació Sanitària Parc Taulí

Spain

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Reumatology Service

Bellvitge University Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Clinical Pharmacology Department, Area del Medicament, Hospital Clínic de Barcelona

Spain

First published: 29/03/2010

Last updated: 24/08/2023

Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Consorci Corporació Sanitària Parc Taulí

Spain

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Hospital Universitario Príncipe de Asturias

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Hospital Universitario Central de Asturias Oviedo, Asturias, Spain, Hospital Monte Naranco Oviedo, Asturias, Spain, Hospital General de Llerena-Zafra Llerena, Badajoz, Spain, Hospital Universitario de Bellvitge Hospitalet de Llobregat, Barcelona, Spain, Corporació Sanitària Parc Taulí Sabadell, Barcelona, Spain, Hospital de Sant Joan Despí Moisès Broggi Sant Joan Despí, Barcelona, Spain, Hospital Comarcal de Palamós Palamós, Girona, Spain, Hospital Son Llàtzer Palma de Mallorca, Illes Balears, Spain, Hospital Universitario de Gran

Canaria Dr. Negrín Las Palmas de Gran Canaria, Las Palmas, Spain, Hospital Universitario Príncipe de Asturias Alcalá de Henares, Madrid, Spain

Networks

GRESSER-SEFC (REDES)

Contact details

Study institution contact

Caridad Pontes

Study contact

cpontes@tauli.cat

Primary lead investigator

Jordi Gratacós

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/01/2012

Study start date
Planned: 02/07/2012

Actual: 02/07/2012

Data analysis start date
Planned: 19/12/2014

Date of final study report
Planned: 30/09/2015

Sources of funding

- Other

More details on funding

Instituto de Salud Carlos III

Study protocol

02 Protocolo_REDES_ 15 diciembre (1)_Version final.pdf(529.02 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Clinical trial

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

The purpose of this study is to demonstrate that patients with Spondylarthropathies in remission under antiTNF therapy, can maintain the remission with a maintenance dose inferior to the currently recommended dose schedule.

Study Design

Clinical trial randomisation

Randomised clinical trial

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AB02) infliximab

infliximab

Medical condition to be studied

Spondyloarthropathy

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

190

Study design details

Outcomes

1) Proportion of patients who are kept in the acceptable therapeutic objective according Spanish Rheumatology Society (SER)consensus, after 1 year, not designated as safety issue 2) Proportion of patients who are kept in acceptable therapeutic objective according SER consensus (BASDAI < 4, globaclinical impression by physician <4, by patient < 4 and axial nocturnal pain <4) after 1 year. 1) Proportion of patients in remission one year after inclusion in the study, not as safety issue2) Proportion of patients in remission, defined as ASDAS-C score <1.3, after 1 year from inclusion 3) Proportion of patients who experience a clinical reactivation (up to 3 years or December 2014) And other 8 secondary outcomes.

Data analysis plan

Study main objective of non-inferiority will be assessed by estimating the between treatment difference rate (95% confidence interval (95%CI)) and, checking it against the pre-defined non-inferiority margin of 17%. Rates will be estimated using a log-binomial regression model including the treatment and the stratification factor. In the unexpected event that the model does not fit, the Poisson link distribution function will be used instead. A sensibility analysis

will be conducted using the Mantel-Haenzel method. Time to decompensation will be estimated by the Kaplan-Meier approach and treatments will be compared with the stratified log-rank test, Cox regression models will be used to estimate Hazard Risks and 95%CI. Rest of variables will be compared depending on type of variables: the Fisher’s exact text for nominal variables, for quantitative variables with Gaussian distribution, the Student's t-test, and for ordinal and continuous non Gaussian variables, the Mann-Whitney test.

Documents

Study, other information

DSMB REDES.pdf(542.48 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No