

A MULTICENTER, OBSERVATIONAL POST-MARKET CLINICAL FOLLOW-UP STUDY IN PATIENTS WITH RA, PsA, OR axSpA ASSESSING THE PATIENT EXPERIENCE WITH THE CIMZIA AVA DEVICE OR OTHER TNF-BLOCKER AUTO-INJECTOR DEVICES

First published: 03/12/2019

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Study

Finalised

Administrative details

EU PAS number

EUPAS32246

Study ID

32247

DARWIN EU® study

No

Study countries

- Belgium
 - Germany
 - Italy
 - Spain
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Study description

This observational post-market clinical follow-up (PMCF) device study is designed to assess utility and use of auto-injection devices available on the market for administration of tumor necrosis factor (TNF)-blocking agents in patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) or axial spondyloarthritis (axSpA), specifically of the certolizumab pegol (CZP) ava device (ava) and other auto-injectors.

Study status

Finalised

Contact details

Study institution contact

Clinical Trial Registries and Results Personal identifiable data of lead investigator are not published here, as consent according to Section 4a of the German Federal Act on Data Protection is not available. clinicaltrials@ucb.com

Study contact

clinicaltrials@ucb.com

Primary lead investigator

Clinical Trial Registries and Results Personal identifiable data of lead investigator are not published here, as consent

according to Section 4a of the German Federal Act on Data Protection is not available.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/03/2019

Study start date

Actual: 15/11/2019

Date of final study report

Actual: 19/05/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

UCB Biopharma S.R.L.

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:

Non-interventional study

Scope of the study:

Other

If 'other', further details on the scope of the study

Assess utility and use of auto-injection devices available on the market for administration of tumor necrosis factor (TNF)-blocking agents in patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) or axial spondyloarthritis (axSpA)

Main study objective:

Assess the patients' satisfaction with self-injection by either ava or other auto-injector devices for administration of a tumor necrosis factor (TNF)-blocking agent at observational point 1 (OP1, about 3 months after device prescription), using 6 questions of the post-self-injection assessment questionnaire (SIAQ) V2.1 satisfaction domain

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-approval study on Device utilisation

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

CERTOLIZUMAB PEGOL

Medical condition to be studied

Rheumatoid arthritis

Psoriatic arthropathy

Axial spondyloarthritis

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)
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Estimated number of subjects

200

Study design details

Outcomes

The summary score describing patient's satisfaction with self-injection as calculated from 6 questions (Q15, and Q17 to Q21) of the post-self-injection assessment questionnaire (SIAQ) V2.1 satisfaction domain documented about 3 months (OP1) after device prescription, The time in days from initial prescription to discontinuation of device use at about 12 months (360 days) after device prescription (persistence of use)

Data analysis plan

This is an exploratory study design without any formal statistical hypothesis testing. The study will estimate the true population proportion or mean of self-injection related endpoints for each device group separately (ava and all other devices). Data will be appropriately summarized and analyzed using tabulation and graphs with respect to demographic/baseline characteristics, disposition, utility/safety observations and other measurements. Summary statistics for continuous variables will include: number of available observations, mean with 95% confidence interval (CI), standard deviation (SD), minimum, median, and maximum. For categorical variables, the number and proportion of patients will be presented. Time-to-event variables will be summarized by Kaplan- Meier analyses.

Documents

Study results

[DV0005-synopsis-public-PDFA.pdf](#) (669.44 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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