Analysis of BLyS-dependent signatures and biology in the intestinal mucosa of patients with inflammatory bowel disease

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Study Finalised

Administrative details

EU PAS number

EUPAS46820

Study ID

46821

DARWIN EU® study

No

Study countries

Spain

Study status

Finalised

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 17/02/2020

Study start date

Actual: 18/02/2020

Date of final study report

Actual: 29/03/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKlein Research and Development Limited

Study protocol

Protocol A. Salas GSK v1 25062019 clean.pdf (113.8 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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Ex vivo response to drug of patient intestinal biopsies

Data collection methods:

Primary data collection

Main study objective:

The overall objective of this proposal is to lay the groundwork for further clinical investigation of anti-BAFF antibodies for the treatment of IBD.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-observational without drug

Study drug and medical condition

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

BELIMUMAB

Medical condition to be studied

Inflammatory bowel disease

Population studied

Short description of the study population

Patients’ inclusion criteria

Patients males and females aged 18 years of age or older manifesting a diagnosed IBD (for at least 3 months prior to screening) with active inflammation (UC patients with a Mayo Endoscopic score of ≥2 and CD patients with a SES-CD score ≥7)

Patients’ exclusion criteria

1) A diagnosis for an active serious infection, including localized infections

2) Any condition or disorder that, in the opinion of the investigator, might confound the study results or pose additional risk to the subject

3) Any contraindications for one or more biopsy collection

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)

Special population of interest

Immunocompromised

Estimated number of subjects

50

Study design details

Data analysis plan

Transcriptional and protein expression data will be collected from each biopsy cultured ex vivo. Comparison of gene and protein expression under different stimulatory or inhibitory conditions will be performed.GraphPad Prism version v8.3 software was used for all statistical analyses. Comparison between two groups was assessed using the Student’s T-test, 2-tailed parametric and unpaired analysis. One-way ANOVA was used for comparisons of more than two groups. For explant culture analysis, fold changes relative to the control condition were transformed to logarithm in base 2, and values were assessed by a parametric One-sample T test. P values < 0.05 were considered statistically significant. Only significant values are labelled in the graphs. Levels of significance are labelled as follows: * = p < 0.05, ** = p < 0.001, *** = p < 0.001, **** p ≤ 0.0001.

Documents

Study results

FINAL REPORT_2022.pdf (2.37 MB)

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