

# A randomized, subject and investigator blinded, placebo controlled, multi-center study in parallel groups to assess the efficacy and safety of CJM112 in patients with moderate to severe inflammatory acne

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Epidermal and dermal conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON47130

### Source

ToetsingOnline

### Brief title

CCJM112X2203

### Condition

- Epidermal and dermal conditions

### Synonym

acne

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Novartis

**Source(s) of monetary or material Support:** Novartis Pharma B.V. (sponsor van dit onderzoek)

## Intervention

**Keyword:** Acne, CJM112, Efficacy, Safety

## Outcome measures

### Primary outcome

To assess the efficacy of CJM112 versus placebo on facial inflammatory lesion counts in patients with moderate to severe inflammatory acne

### Secondary outcome

To assess the safety and tolerability of CJM112 in patients with moderate to severe inflammatory acne.

To assess the pharmacokinetics of CJM112 in patients with moderate to severe acne

## Study description

### Background summary

Moderate to severe inflammatory acne is a debilitating disease, with visible inflammatory lesions on the face and subsequent risk of permanent scars. The current treatment is often a combination or association of several topical treatments (such as topical retinoids and antibacterials such as benzoylperoxide and antibiotics) with oral antibiotics, and/or hormonal treatment or retinoids, such as isotretinoin. It is more and more recognized that inflammatory acne is not an infectious disease, but rather an inflammatory skin disease, in which *Propionibacterium acnes* (*P. acnes*) and innate immunity play critical roles. Recently the role of IL-17A in early acne lesions has been demonstrated by upregulated IL-17A in lesional versus

non-lesional acne skin, both at RNA as well as at protein level. Serum IL17A is increased in acne patients and reduced by effective treatment after 12 weeks (Karadag et al 2012).

CJM112 is an affinity matured fully human monoclonal antibody (mAb) that demonstrates high affinity to IL-17A and IL-17AF

## **Study objective**

The study is designed primarily to assess preliminary efficacy and safety of CJM112 in patients with moderate to severe inflammatory acne and to determine if CJM112 has an adequate clinical profile for further clinical development. In addition, sustainability of response and dose relationship will be explored.

## **Study design**

This is a randomized, subject and investigator blinded, placebo controlled, multi-center study in parallel groups.

Subject receives:

Period 1 (8 weeks): CJM112 high dose (300 mg) monthly

Period 2 (12 weeks): CJM112 high dose (300 mg) monthly

Treatment arm 2:

Period 1 (8 weeks): CJM112 low dose (75 mg) monthly

Period 2 (12 weeks): CJM112 low dose (75 mg) monthly

Treatment arm 3:

Period 1 (8 weeks): Placebo monthly

Period 2 (12 weeks): CJM112 high dose (300 mg) or CJM112 low dose (75 mg) monthly

## **Intervention**

CJM112 or placebo.

## **Study burden and risks**

Study period: 11 months, 10 visits, varying from 2-4 hours per visit

Physical examination: 7 times

Blood pressure, pulse and body temperature: 10 times

Blood and urine collection: 10 times

ECG: 6 times

Imaging: 5 times

Measuring sebum face skin (sebumeter): 4 times

Completion of 3 questionnaires: 4 times

For CHDR only: During treatment and follow-up period: Daily selfie via special app.

Optional:  
Blood collection for pharmacogenetic examination  
Skin biopt (optional): 3 times

Forbidden co-medication.

## Contacts

### Public

Novartis

Raapopseweg 1  
Arnhem 6824 DP  
NL

### Scientific

Novartis

Raapopseweg 1  
Arnhem 6824 DP  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)  
Elderly (65 years and older)

### Inclusion criteria

- Male and female subjects aged 18 to 45 years of age included.
- Body weight between 50 and 120 kg, inclusive, at screening.
- Patients with papulo-pustular acne vulgaris with between 25 and 100 facial inflammatory lesions (papules, pustules and nodules), and presence of non-inflammatory lesions (open and closed comedones) in the face, at screening and baseline, who have failed systemic therapy

4 - A randomized, subject and investigator blinded, placebo controlled, multi-center ... 25-05-2025

for inflammatory acne.

-No more than 5 facial inflammatory nodules, at screening and baseline.

-Investigator's Global assessment (IGA) score of at least moderate (3) acne severity on the face, at screening and baseline.

## Exclusion criteria

- Use of investigational drugs at the time of screening, or within 4 weeks or 5 half-lives of baseline, whichever is longer; or longer if required by local regulations.

- Use of any topical anti-acne prescription treatment within 2 weeks and any over the counter (OTC) anti-acne treatment within 1 week of baseline (use of medicated (anti-acne) creams, medicated cleansers or medicated soaps is prohibited for the duration of the study for treatment period 1).

- Use of any oral/systemic treatment for acne, including oral antibiotics, dapsone, oral zinc within 4 weeks prior to baseline.

-Use of systemic or lesional injected (for acne) corticosteroids or systemic immunomodulators (such as cyclosporine, methotrexate, azathioprine, etc.) within 4 weeks before baseline

-Use of any systemic hormonal treatment (in particular anti-androgens, such as spironolactone, finasteride and cyproterone acetate) within 1 month before baseline. Oral contraceptives can be continued if stable for the last 3 months before baseline and if stable in dose and dosing regimen and type (brand) and if the patient plans to continue throughout the study period.

-Previous treatment with biologics (such as anti-TNF\* agents or anti-IL-1) within 3 months prior to baseline; Anti-IL-12/23 blocking agents (such as briakinumab and ustekinumab or p19 antibodies) within 6 months prior to baseline.

- Any previous treatment with IL-17 or IL17R blocking agents, including, but not limited to secukinumab, ixekizumab, bimekizumab or brodalumab.

-Use of oral retinoids (in particular isotretinoin) within the last 6 months prior to baseline.

-Use of facial medium depth chemical peels (excluding home regimens) within 3 months prior to baseline.

-Patients with known active Crohn\*s disease

## Study design

### Design

Study phase: 2

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	22-12-2016
Enrollment:	30
Type:	Actual

## Medical products/devices used

Product type:	Medicine
Brand name:	CJM112
Generic name:	CJM112

## Ethics review

Approved WMO	
Date:	12-10-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO	
Date:	06-12-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO	
Date:	07-12-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO	
Date:	26-01-2017
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	07-02-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	09-06-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	29-08-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	26-10-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	21-11-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	22-02-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	07-03-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
EudraCT	EUCTR2016-002492-95-NL
ClinicalTrials.gov	NCT02998671
CCMO	NL58510.056.16