



## Clinical trial results:

**Prospective, open-label, single-arm, single-center phase IV clinical trial to evaluate efficacy and safety of the adalimumab biosimilar Amgevita in subjects with moderate to severe active chronic inflammatory bowel disease (Crohn's disease and ulcerative colitis)**

### Summary

EudraCT number	2019-003662-40
Trial protocol	DE
Global end of trial date	07 March 2022

### Results information

Result version number	v1 (current)
This version publication date	09 August 2024
First version publication date	09 August 2024

### Trial information

#### Trial identification

Sponsor protocol code	UKER-AMGEVITA-CED-NOVO-01
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

### Sponsors

Sponsor organisation name	Universitätsklinikum Erlangen
Sponsor organisation address	Maximiliansplatz 2, Erlangen, Germany, 91054
Public contact	Medizinische Klinik 1, Universitätsklinikum Erlangen, raja.atreya@uk-erlangen.de
Scientific contact	Medizinische Klinik 1, Universitätsklinikum Erlangen, raja.atreya@uk-erlangen.de

Notes:

### Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 March 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 March 2022
Global end of trial reached?	Yes
Global end of trial date	07 March 2022
Was the trial ended prematurely?	Yes

Notes:

## General information about the trial

Main objective of the trial:

To investigate efficacy of adalimumab biosimilar (Amgevita) in subjects with moderate to severe active chronic inflammatory bowel disease (Crohn's disease and ulcerative colitis)

Protection of trial subjects:

To limit the risk of side effects, amgevita was used according to its SmPC, furthermore the patients on drug were closely monitored during trial participation.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 December 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	20
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

male or female subjects, 18-80 years of age, diagnosis of chronic inflammatory bowel disease with indication for initial treatment with adalimumab in subjects with moderate to high grade disease activity and clinically insufficient response to or contraindication for systematic therapy with corticosteroids and/or immunosuppressants

### Period 1

Period 1 title	Treatment period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

no blinding

### Arms

Arm title	All subjects
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Arm description:

All subjects who have received Amgevita at least once

Arm type	Experimental
Investigational medicinal product name	Amgevita
Investigational medicinal product code	
Other name	biosimilar adalimumab
Pharmaceutical forms	Solution for injection in pre-filled pen, Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

induction: day 1: 160 mg s.c., day 15: 80 mg s.c.

maintainance: 40 mg s.c. every 14 days (starting from day 29)

Number of subjects in period 1	All subjects
Started	20
Completed	5
Not completed	15
Adverse event, non-fatal	1
early study termination	13
Lack of efficacy	1

## Baseline characteristics

### Reporting groups

Reporting group title	Treatment period
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Reporting group description: -

Reporting group values	Treatment period	Total	
Number of subjects	20	20	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	20	20	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	11	11	
Male	9	9	

## End points

### End points reporting groups

Reporting group title	All subjects
Reporting group description: All subjects who have received Amgevita at least once	

### Primary: Clinical response to Amgevita in patients with moderate to severe CED

End point title	Clinical response to Amgevita in patients with moderate to severe CED <sup>[1]</sup>
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End point description:

End point type	Primary
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End point timeframe:

at week 13 after onset of therapy

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: no statistical analyses due to small number of study participants (early termination after enrollment of 20 [planned 87] subjects due to poor recruitment)

End point values	All subjects			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: subject				
Responder	18			
Non-Responder	2			

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

from Day 1 (visit 2) until week 52 (visit 7, EoS)

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	27
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### Reporting groups

Reporting group title	Safety Analysis Set
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Reporting group description:

all subjects who have received the IMP at least once

Serious adverse events	Safety Analysis Set		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 20 (5.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Gastrointestinal disorders			
Ileus			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Safety Analysis Set		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 20 (80.00%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
General disorders and administration site conditions			
Application site reaction			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		

Fatigue subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Influenza like illness subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2		
Rhinorrhoea subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Investigations C-reactive protein increased subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2		
Faecal calprotectin increased subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 4		
Injury, poisoning and procedural complications Anastomotic ulcer subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Rib fracture subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Skin laceration subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Nervous system disorders			

Headache			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	2		
Intercostal neuralgia			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	2		
Migraine			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Paraesthesia			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Sciatica			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	2		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Crohn's disease			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Dysphagia			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Nausea			



subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Cutaneous symptom			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Drug eruption			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Eczema			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Pain in extremity			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Infections and infestations			
COVID-19			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Cystitis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Nasopharyngitis			

subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Oral herpes			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Tonsillitis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Vaginal infection			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 May 2021	A01-SAM-CSP-AMGEVITA: IC: endoscopic diagnostic also accepted if more than 6 (up to 12) weeks prior to screening

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Early termination due to poor recruitment after 20 (instead of 87) subjects
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Notes: