Clinical trial results:
A non-inferiority study on dose reduction of adalimumab in psoriasis patients who are overtreated.

Summary

EudraCT number	2019-001918-42
Trial protocol	BE
Global end of trial date	22 March 2022

Results information

Result version number	v1 (current)
This version publication date	02 August 2024
First version publication date	02 August 2024
Summary attachment (see zip file)	Final Study Report (2019-001918-42_Final_study_report_SUPRA-A.pdf)

Trial information

Trial identification

Sponsor protocol code	TDM-ADA2019

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04028713
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UZ Gent - HIRUZ
Sponsor organisation address	C. Heymanslaan 10, Gent, Belgium, 9000
Public contact	HIRUZ CTU, Ghent University Hospital, hiruz.ctu@uzgent.be
Scientific contact	HIRUZ CTU, Ghent University Hospital, 32 093320530, hiruz.ctu@uzgent.be

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	22 March 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 March 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

- The proportion of patients in each group in clinical remission (absolute PASI < 2) at year 1 after optimization (non-inferiority of intervention)
- Optimization of extraction protocol for adalimumab serum trough levels and anti-drug antibodies (ADA) derived from micro-sampling technique.

Protection of trial subjects:

See attachment Final Study Report

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 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	Belgium: 19
Worldwide total number of subjects	19
EEA total number of subjects	19

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)	16
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

See attachment Final Study Report

Pre-assignment

Screening details:

See attachment Final Study Report

Period 1

Period 1 title	Overal Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Investigator[1]

Blinding implementation details:

See attachment Final Study Report

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention

Arm description:

See attachment Final Study Report

Arm type	Active comparator
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

See attachment Final Study Report

Arm title	Standard dosing arm

Arm description:

See attachment Final Study Report

Arm type	Active comparator
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

See attachment Final Study Report

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: See attachment Final Study Report

Number of subjects in period 1[2]	Intervention	Standard dosing arm
Started	6	4
Completed	6	4

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: See attachment Final Study Report

Baseline characteristics

End points

End points reporting groups

Reporting group title	Intervention
Reporting group description:	
See attachment Final Study Report	
Reporting group title	Standard dosing arm
Reporting group description:	
See attachment Final Study Report	

Primary: Primary

End point title	Primary[1]
End point description:	
See attachment Final Study Report	
End point type	Primary
End point timeframe:	
During the study	

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: For statistical analyses, see attachment Final Study Report

End point values	Intervention	Standard dosing arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	4		
Units: Patients	6	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Secondary

End point title	Secondary
End point description:	
See attachment Final Study Report	
End point type	Secondary
End point timeframe:	
During the study	

End point values	Intervention	Standard dosing arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	4		
Units: Patients	6	4		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
During the study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: See attachment Final Study Report

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported