Clinical trial results:
A randomised, active comparator, double-blind, multi centre, parallel, phase 2a trial, investigating the mechanism of action of NNC0109-0012 (anti-IL-20 mAb) through synovial biopsies in subjects with rheumatoid arthritis and an inadequate response to Methotrexate

Summary

EudraCT number	2013-001492-20
Trial protocol	IE GB ES PT
Global end of trial date	11 August 2014

Results information

Result version number	v1 (current)
This version publication date	26 July 2020
First version publication date	26 July 2020
Summary attachment (see zip file)	Cancelled before Active Statement (Cancelled before Active Statement_2013-001492-20.pdf)

Trial information

Trial identification

Sponsor protocol code	NN8226-4064

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02097264
WHO universal trial number (UTN)	U1111-1141-3512

Notes:

Sponsors

Sponsor organisation name	Novo Nordisk A/S
Sponsor organisation address	Novo Allé, Bagsvaerd, Denmark, 2880
Public contact	Clinical Reporting Anchor and Disclosure (1452), Novo Nordisk A/S, clinicaltrials@novonordisk.com
Scientific contact	Clinical Reporting Anchor and Disclosure (1452), Novo Nordisk A/S, clinicaltrials@novonordisk.com

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	11 August 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 August 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To explore the potential differences in the mechanism of action through analysis of synovial biopsies in subjects with active rheumatoid arthritis (RA) and an inadequate response to methotrexate (MTX) after 12 weeks of treatment with NNC0109-0012 and adalimumab

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 August 2014
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	United Kingdom: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

Pre-assignment

Screening details:

N/A

Period 1

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

Blinding implementation details:

N/A

Arms

Arm title	NNC0109-0012

Arm description:

NNC0109-0012 drug product 100mg/mL

Arm type	Experimental
Investigational medicinal product name	NNC0109-0012
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Not mentioned

Dosage and administration details:

99999

Number of subjects in period 1	NNC0109-0012
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	Overall Study

Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	99999	99999	
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)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender Categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	NNC0109-0012
Reporting group description:	
NNC0109-0012 drug product 100mg/mL	

Primary: Change in the total histopathological synovitis score

End point title	Change in the total histopathological synovitis score[1]
End point description:	
99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.	
End point type	Primary
End point timeframe:	
N/A	

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 subjects were enrolled in the trial hence results are not available

End point values	NNC0109-0012			
Subject group type	Reporting group			
Number of subjects analysed	99999			
Units: N/A	99999			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All adverse events occuring during the course of the clinical trial were to be collected.

Adverse event reporting additional description:

N/A

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Reporting groups

Reporting group title	NNC0109-0012

Reporting group description:

NNC0109-0012 drug product 100mg/mL

Serious adverse events	NNC0109-0012		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	NNC0109-0012		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		

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: No subjects were enrolled in the trial hence results are not available

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

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

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial

Notes: