



Clinical trial results:

The effect of BM32, a recombinant hypoallergenic vaccine for immunotherapy of grass pollen allergy, on immunoglobulin levels in nasal secretions of patients suffering from seasonal allergic rhinitis

Summary

EudraCT number	2012-004194-12
Trial protocol	AT
Global end of trial date	21 November 2014

Results information

Result version number	v1 (current)
This version publication date	04 November 2020
First version publication date	04 November 2020

Trial information

Trial identification

Sponsor protocol code	CS-BM32-nasal-001
-----------------------	-------------------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Währinger Gürtel 18-20, Vienn, Austria, 1090
Public contact	HNO Klinik, Medizinische Universität Wien, +43 1404003438, verena.niederberger@meduniwien.ac.at
Scientific contact	HNO Klinik, Medizinische Universität Wien, +43 1404003438, verena.niederberger@meduniwien.ac.at

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	Interim
Date of interim/final analysis	15 October 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 November 2014
Global end of trial reached?	Yes
Global end of trial date	21 November 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effect of immunotherapy with the recombinant hypoallergenic vaccine, BM32, compared to placebo, on allergen-specific Ig levels in nasal secretion during 2 consecutive treatment years.

Protection of trial subjects:

patients were attending the outpatient department for their visits and could contact the primary investigator or the department any time

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 December 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 38
Worldwide total number of subjects	38
EEA total number of subjects	38

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)	38
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients participating in the study CS-BM32-003 (EK 1104/2012) were recruited by personal contact.

Pre-assignment

Screening details:

Inclusion criteria:

- Positive history of grass pollen allergy, positive skin prick test reaction to grass pollen extract, grass pollen allergen-specific IgE and rPhl p 1/rPhl p 5-specific IgE (at least 3.5 kUA/L) at the screening visit of CS-BM32-003 or within 12 months prior to the screening visit of CS-BM32-003

Period 1

Period 1 title	Main study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer

Blinding implementation details:

Blinding was performed in main study

Arms

Are arms mutually exclusive?	Yes
Arm title	BM32

Arm description:

BM32

Arm type	Active comparator
Investigational medicinal product name	BM32
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

s.c.

Arm title	Placebo
------------------	---------

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

s.c.

Number of subjects in period 1	BM32	Placebo
Started	28	10
Completed	24	10
Not completed	4	0
no interest	4	-

Baseline characteristics

Reporting groups

Reporting group title	BM32
-----------------------	------

Reporting group description:

BM32

Reporting group title	Placebo
-----------------------	---------

Reporting group description: -

Reporting group values	BM32	Placebo	Total
Number of subjects	28	10	38
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	28	10	38
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	17	5	22
Male	11	5	16

End points

End points reporting groups

Reporting group title	BM32
Reporting group description: BM32	
Reporting group title	Placebo
Reporting group description: -	

Primary: Ig levels in nasal secretions

End point title	Ig levels in nasal secretions ^[1]
End point description:	

End point type	Primary
----------------	---------

End point timeframe:

Treatment year one:

- Visit 1: before the 1st pre-seasonal vaccination
- Visit 2: after the 3rd pre-seasonal vaccination
- Visit 3: in the middle of the grasspollen season
- Visit 4: 2 weeks after the end of the grass pollen sea

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 statistic

End point values	BM32	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28 ^[2]	10 ^[3]		
Units: OD				
geometric mean (standard deviation)	0.0 (\pm 0.0)	0.0 (\pm 0.0)		

Notes:

[2] - no statistic

[3] - no statistic

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Adverse events are divided into the categories "serious" and "non-serious". This determines the procedure which must be used to report/document the adverse event

Assessment type	Non-systematic
-----------------	----------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	n.a.
--------------------	------

Frequency threshold for reporting non-serious adverse events: 2 %

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 adverse events

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