



## Clinical trial results: Application of FSME-Immun® in allergic patients Summary

EudraCT number	2012-005672-34
Trial protocol	AT
Global end of trial date	26 March 2018

### Results information

Result version number	v1 (current)
This version publication date	31 January 2020
First version publication date	31 January 2020
Summary attachment (see zip file)	PDF Publikation in Vaccine 2018 (Publikation Vaccine 2018_TBE vaccination in allergic patients.pdf) Supplementary data of Article in Vaccine 2018 (supp. data allergy_vaccine.pdf)

### Trial information

#### Trial identification

Sponsor protocol code	FSME_only_1.1
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02511535
WHO universal trial number (UTN)	-

Notes:

### Sponsors

Sponsor organisation name	Medical University of Vienna, ISPTM
Sponsor organisation address	Kinderspitalgasse 15, Vienna, Austria, 1090
Public contact	ISPTM, Clinical Trials Information, Institut für Spezifische Prophylaxe und Tropenmedizin, +43 140160 38281,
Scientific contact	ISPTM, Clinical Trials Information, Institut für Spezifische Prophylaxe und Tropenmedizin, +43 140160 38281,

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	26 March 2018
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	26 March 2018
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

Humoral immunity, based on TBE Neutralisationstest-Titers one month +/- 7 days after booster

Protection of trial subjects:

proper intra-muscular application of the vaccine, monitoring of patients for 20 min after vaccination on site, diary for documentation of side effects for 7 days after vaccination

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2014
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: 119
Worldwide total number of subjects	119
EEA total number of subjects	119

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)	119
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

- completed primary TBE immunization + at least one booster
- adults of both sexes between 18 and 60 years of age
- willingness to sign written informed consent form

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	allergic patients

Arm description: -

Arm type	Experimental
Investigational medicinal product name	FSME-Immun®
Investigational medicinal product code	J07BA01
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose of FSME-Immun® 0.5 ml; 2.4 micrograms

Route of administration: intramuscular use

<b>Arm title</b>	allergic patients undergoing specific immuno therapy
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	FSME-Immun®
Investigational medicinal product code	J07BA01
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose of FSME-Immun® 0.5 ml; 2.4 micrograms

Route of administration: intramuscular use

<b>Arm title</b>	healthy controls
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Arm description: -

Arm type	Active comparator
Investigational medicinal product name	FSME-Immun®
Investigational medicinal product code	J07BA01
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose of FSME-Immun® 0.5 ml; 2.4 micrograms

Route of administration: intramuscular use

Investigational medicinal product name	FSME-Immun®
Investigational medicinal product code	J07BA01
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose of FSME-Immun® 0.5 ml; 2.4 micrograms

Route of administration: intramuscular use

Number of subjects in period 1	allergic patients	allergic patients undergoing specific immuno therapy	healthy controls
Started	49	21	49
Completed	49	21	49

## Baseline characteristics

### Reporting groups

Reporting group title	overall trail
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Reporting group description: -

Reporting group values	overall trail	Total	
Number of subjects	119	119	
Age categorical			
Adults (18-60 years)			
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)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Adults (18-60 years)	119	119	
Gender categorical			
males and females			
Units: Subjects			
Female	72	72	
Male	47	47	

## End points

### End points reporting groups

Reporting group title	allergic patients
Reporting group description: -	
Reporting group title	allergic patients undergoing specific immuno therapy
Reporting group description: -	
Reporting group title	healthy controls
Reporting group description: -	

### Primary: Humoral immunity, based on TBE Neutralisationstest-Titers one month +/- 7 days after booster

End point title	Humoral immunity, based on TBE Neutralisationstest-Titers one month +/- 7 days after booster <sup>[1]</sup>
End point description:	
End point type	Primary
End point timeframe:	
1 month after booster (+/- 7 days)	

#### 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: Please see statistical analyses in the publication:

"Allergic patients with and without allergen-specific immunotherapy mount protective immune responses to tick-borne encephalitis vaccination in absence of enhanced side effects or propagation of their Th2 bias"

Garner-Spitzer et al, Vaccine 2018 May 11;36 (20):2816-2824. doi: 10.1016/j.vaccine.2018.03.076.

End point values	allergic patients	allergic patients undergoing specific immuno therapy	healthy controls	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	21	49	
Units: titer				
geometric mean (confidence interval 95%)	318 (239 to 423)	250 (144 to 434)	282 (211 to 378)	

### Statistical analyses

No statistical analyses for this end point

### Secondary: cellular immune response

End point title	cellular immune response
End point description:	
IFN-g concentrations in culture supernatants on day 7 after TBE booster	
End point type	Secondary

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End point timeframe:

d0 (before booster vaccination) and 1 week after booster

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<b>End point values</b>	allergic patients	allergic patients undergoing specific immuno therapy	healthy controls	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	21	49	
Units: pg/ml				
geometric mean (confidence interval 95%)	54 (38 to 78)	59 (33 to 108)	77 (52 to 114)	

### **Statistical analyses**

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No statistical analyses for this end point

## Adverse events

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

see publication

Assessment type	Systematic
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### Dictionary used

Dictionary name	in house
Dictionary version	1.1

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

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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 serious adverse events occurred in this study.



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/29673942>