

**Clinical trial results:**

Open, comparative, randomized study on the efficacy, safety and bioavailability of highly concentrated inhaled epinephrine (4 mg L-epinephrine / ml, Infectokrupp® Inhal) versus epinephrine autoinjector application (Fastjekt® Junior) in infants with acute anaphylactic reaction during a food provocation.

**TRANCHE - TReatment of ANaphylaxis in CHildren with Epinephrine  
Summary**

EudraCT number	2014-000097-19
Trial protocol	DE
Global end of trial date	31 December 2024

**Results information**

Result version number	v1 (current)
This version publication date	19 February 2026
First version publication date	19 February 2026

**Trial information****Trial identification**

Sponsor protocol code	TRANCHE
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**Additional study identifiers**

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

Notes:

**Sponsors**

Sponsor organisation name	Charité - Universitätsmedizin Berlin
Sponsor organisation address	Charitéplatz 1, Berlin, Germany, 10115
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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	05 January 2026
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 December 2024
Global end of trial reached?	Yes
Global end of trial date	31 December 2024
Was the trial ended prematurely?	Yes

Notes:

## General information about the trial

Main objective of the trial:

Mean change of anaphylaxis symptom scores (ASC, considered weighted symptoms of the organ systems (CASC) and if necessary use of an additional medicinal anaphylaxis therapy, DASC) evaluated from baseline to endpoint after 20 minutes (for the FA (Full-Analysis-) population)

Protection of trial subjects:

The study was performed in accordance with the ethical principles stated in the Declaration of Helsinki. The study was conducted with agreement with ICG-GCP and other national regulations.

Background therapy:

Anaphylaxis is a severe, life-threatening allergic reaction that requires immediate medical attention. Epinephrine administration as the most critical treatment for anaphylaxis is usually performed intramuscularly. However, there is strong hesitancy for autoinjector use, especially among caregivers, and a need for effective needle-free options. Pharmacokinetic studies in healthy volunteers indicate that systemic absorption of highly concentrated nebulized inhaled epinephrine is rapid and has a good bioavailability, thus can reach therapeutic levels, but data on affected young children was lacking. This observer-blinded, randomized, controlled clinical trial investigated the effectiveness, safety and bioavailability of highly concentrated inhaled nebulized epinephrine (Infectokrupp® Inhal) vs. epinephrine autoinjector use (Fastjekt® Junior) in young children with acute anaphylactic reaction during an oral food challenge.

Evidence for comparator: -

Actual start date of recruitment	09 January 2017
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: 26
Worldwide total number of subjects	26
EEA total number of subjects	26

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	5
Children (2-11 years)	21
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

The study was conducted from August 21, 2017 (FPFV) up to December 9, 2024 (LPLV) at one site in Germany. 141 patients were screened, 26 were randomized and analysed.

### Pre-assignment

Screening details:

Age 1-6 yrs, Anaphylactic reaction requiring treatment in the context of oral food challenges, defined by:

At least 2 affected organ systems (skin, gastrointestinal tract, respiratory tract, and/or cardiovascular system) with an anaphylaxis symptom score of at least 5 points, peripheral or central airway obstruction, reduced sys. blood pressure.

### Period 1

Period 1 title	Intervention period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Due to the different forms of administration (inhalation or intramuscular injection), blinding would have required the additional injection or inhalation of a placebo preparation. This was not done due to the age of the children. However, 10 minutes and 20 minutes after the onset of the anaphylactic reaction requiring intervention, an independent medical assessment of the patient was carried out by another investigator who was "blinded" to the treatment group of the respective patient.

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Infectokrupp - Inhalation

Arm description:

Treatment by inhalation

Arm type	Experimental
Investigational medicinal product name	Epinephrine
Investigational medicinal product code	E4250
Other name	Adrenaline; ATC Code: C01 CA24
Pharmaceutical forms	Solution and dispersion for nebuliser dispersion
Routes of administration	Inhalation use

Dosage and administration details:

1-2 ml (4-8 mg Epinephrin). Infectokrupp® Inhal was inhaled continuously for 10 minutes using a fully filled Infectopharm Pocket Nebulizer®. At a nebulization rate of 2:45 min/ml specified by the Infectopharm pocket nebulizer® used, approximately 3.5 ml of Infectokrupp® Inhal is nebulized, which, taking into account the repeat therapy, is within the dosage recommendation range specified in the product information.

The test medication was administered after an anaphylactic reaction requiring immediate treatment was detected during an oral food challenge. The inclusion criteria regarding age and weight were designed to ensure that the recommended dose of adrenaline was administered with the available test preparations. All patients received standard therapy in the form of (concomitant) intravenous administration of antihistamines (clemastine intravenously (Tavegil®) at a dosage of 0.5 mg for children weighing less than 25 kg and 1.0 mg for children weighing 25 kg or more).

<b>Arm title</b>	Fastjekt - Injection
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Arm description:

Treatment by intramuscular injection

Arm type	Active comparator
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Investigational medicinal product name	Epinephrin
Investigational medicinal product code	E4250
Other name	Adrenalin, ATC Code: C01 CA24
Pharmaceutical forms	Solution for injection
Routes of administration	Injection

Dosage and administration details:

The pediatric dosage for children weighing 7.5–25 kg for emergency allergy treatment was 150 micrograms of epinephrine (adrenaline) injected intramuscularly using an auto-injector "Fastjekt® Junior".

All patients received standard therapy in the form of (concomitant) intravenous administration of antihistamines (clemastine intravenously (Tavegil®) at a dosage of 0.5 mg for children weighing less than 25 kg and 1.0 mg for children weighing 25 kg or more) and systemic glucocorticoid (prednisolone (Decortin®) at a dosage of 5 mg/kg body weight). In cases of clinically relevant blood pressure drop, intravenous administration of volume (20 ml/kg body weight NaCl 0.9%) was possible; in cases of clinically relevant bronchial obstruction, 2 puffs of salbutamol metered dose inhaler via inhalation aid (spacer) were administered.

<b>Number of subjects in period 1</b>	Infectokrupp - Inhalation	Fastjekt - Injection
Started	13	13
Completed	13	13

## Baseline characteristics

### Reporting groups

Reporting group title	Infectokrupp - Inhalation
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Reporting group description:

Treatment by inhalation

Reporting group title	Fastjekt - Injection
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Reporting group description:

Treatment by intramuscular injection

Reporting group values	Infectokrupp - Inhalation	Fastjekt - Injection	Total
Number of subjects	13	13	26
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)	2	3	5
Children (2-11 years)	11	10	21
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	3.92	3.46	
standard deviation	± 1.75	± 1.81	-
Gender categorical Units: Subjects			
Female	6	5	11
Male	7	8	15
Weight Units: kg			
arithmetic mean	18.01	16.36	
standard deviation	± 4.66	± 5.13	-

## End points

### End points reporting groups

Reporting group title	Infectokrupp - Inhalation
Reporting group description:	
Treatment by inhalation	
Reporting group title	Fastjekt - Injection
Reporting group description:	
Treatment by intramuscular injection	

### Primary: change ASC

End point title	change ASC
End point description:	Mean change in anaphylaxis symptom score (ASC, weighted to take into account symptoms in the organ systems (CASC) and any necessary additional medical treatment for anaphylaxis (DASC)) from baseline to the endpoint after 10 minutes.
End point type	Primary
End point timeframe:	from Baseline up to 10 minutes after intervention

End point values	Infectokrupp - Inhalation	Fastjekt - Injection		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	13		
Units: Score				
arithmetic mean (standard deviation)				
ASC baseline	11 ( $\pm$ 3.7)	10.23 ( $\pm$ 3.06)		
ASC after 10 min	2.77 ( $\pm$ 2.77)	2.15 ( $\pm$ 2.61)		

### Statistical analyses

Statistical analysis title	Inhalation vs. Injection Group
Statistical analysis description:	The comparison of the mean values of the end-baseline differences between the intramuscular and inhalation groups was exploratory and non-confirmatory
Comparison groups	Infectokrupp - Inhalation v Fastjekt - Injection
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.9161
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)

Confidence interval	
level	95 %



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

overall trial

Assessment type	Systematic
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### Dictionary used

Dictionary name	CTCAE
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Dictionary version	5.0
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### Reporting groups

Reporting group title	Inhalation Group
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Reporting group description: -

Reporting group title	Injektion Group
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Reporting group description: -

Serious adverse events	Inhalation Group	Injektion Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)	1 / 13 (7.69%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Immune system disorders			
Anaphylactic reaction	Additional description: additional i.m. injection of adrenalin was given		
subjects affected / exposed	0 / 13 (0.00%)	1 / 13 (7.69%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Inhalation Group	Injektion Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 13 (84.62%)	0 / 13 (0.00%)	
Investigations			
Lost of taste sensation			
subjects affected / exposed	3 / 13 (23.08%)	0 / 13 (0.00%)	
occurrences (all)	3	0	
Olfactory dysfunction			
subjects affected / exposed	1 / 13 (7.69%)	0 / 13 (0.00%)	
occurrences (all)	1	0	

increased salivation subjects affected / exposed occurrences (all)	4 / 13 (30.77%) 4	0 / 13 (0.00%) 0	
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 13 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Scratchy throat subjects affected / exposed occurrences (all)  Cough subjects affected / exposed occurrences (all)	3 / 13 (23.08%) 3  5 / 13 (38.46%) 5	0 / 13 (0.00%) 0  0 / 13 (0.00%) 0	
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)  Urticaria subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1  1 / 13 (7.69%) 1	0 / 13 (0.00%) 0  0 / 13 (0.00%) 0	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 November 2016	The protocol (Version 1.0, dated 01.08.2016) was updated : <ul style="list-style-type: none"><li>- change in case number planning and statistical analysis</li><li>- change of schedule and risk management</li></ul>
25 October 2017	-protocol update: <ul style="list-style-type: none"><li>- extension of the duration of study</li><li>- change of inclusion criteria (update product information for the study preparation PR2 "Fastjekt Junior")</li></ul>
08 January 2020	update Protocol Version 2.1 (21/11/2019), extension of study duration
26 May 2021	update protocol V 3.0 (31./03/2021); extension study duration due to the time lost during the coronavirus pandemic, Identification of AE as possible reasons for protocol violations during the study, e.g., shortened inhalation times.
28 July 2021	update SmPC of "FASTJEKT Junior" and update IB of KruppInhal

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.

There were temporary interruptions or reductions in the inhalation time during inhalation.

Notes: