



## Clinical trial results:

### Summary

EudraCT number	0004-000245-38
Trial protocol	FR
Global end of trial date	

### Results information

Result version number	v1 (current)
This version publication date	
First version publication date	

### Trial information

#### Trial identification

Sponsor protocol code	
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#### Additional study identifiers

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

Notes:

### Sponsors

Notes:

### Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	
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	
Date of interim/final analysis	
Is this the analysis of the primary completion data?	
Global end of trial reached?	No

Notes:

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**General information about the trial**

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Main objective of the trial:

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Protection of trial subjects:

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Background therapy: -

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Evidence for comparator: -

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Actual start date of recruitment	
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Long term follow-up planned	No
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Independent data monitoring committee (IDMC) involvement?	
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Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

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Notes:

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**Subjects enrolled per age group**

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In utero	
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Preterm newborn - gestational age < 37 wk	
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Newborns (0-27 days)	
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Infants and toddlers (28 days-23 months)	
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Children (2-11 years)	
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Adolescents (12-17 years)	
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Adults (18-64 years)	
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From 65 to 84 years	
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85 years and over	
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## Subject disposition

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### Recruitment

Recruitment details: -

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### Pre-assignment

Screening details: -

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## End points

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### End points reporting groups

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## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Timeframe for AE

Adverse event reporting additional description:

AE additional description

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.0
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### Reporting groups

Reporting group title	Control
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Reporting group description: -

Reporting group title	Experimental
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Reporting group description: -

<b>Serious adverse events</b>	Control	Experimental	
<b>Total subjects affected by serious adverse events</b>			
subjects affected / exposed	15 / 99 (15.15%)	33 / 101 (32.67%)	
number of deaths (all causes)	12	27	
number of deaths resulting from adverse events	9	22	
<b>Vascular disorders</b>			
<b>Pulmonary embolism</b>			
subjects affected / exposed	1 / 99 (1.01%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Deep vein thrombosis</b>			
subjects affected / exposed	1 / 99 (1.01%)	3 / 101 (2.97%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
<b>Surgical and medical procedures</b>			
<b>Aortic valve replacement</b>			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cholecystectomy</b>			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to	0 / 0	0 / 1	

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryocystorhinostomy			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip arthroplasty			
subjects affected / exposed	1 / 99 (1.01%)	2 / 101 (1.98%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Small intestinal resection			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder papilloma			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Vasculitis			
subjects affected / exposed	1 / 99 (1.01%)	2 / 101 (1.98%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Pulmonary vasculitis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Psychiatric disorders			
Conversion disorder			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Investigations			
Medical observation			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
B-cell lymphoma			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			

Pneumonia staphylococcal			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Pneumonia klebsiella			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Pneumonia viral			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Laryngeal stenosis			
subjects affected / exposed	0 / 99 (0.00%)	2 / 101 (1.98%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary embolism			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumomediastinum			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sleep apnoea syndrome			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophageal spasm			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophagitis			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 99 (1.01%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	

deaths causally related to treatment / all	0 / 1	0 / 0	
Hyperkalaemia			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Gastroenteritis Escherichia coli			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Influenza			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lower respiratory tract infection			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Escherichia urinary tract infection			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 99 (0.00%)	2 / 101 (1.98%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	

deaths causally related to treatment / all	0 / 0	1 / 2	
Pneumonia			
subjects affected / exposed	0 / 99 (0.00%)	3 / 101 (2.97%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	

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

<b>Non-serious adverse events</b>	Control	Experimental	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 99 (15.15%)	24 / 101 (23.76%)	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
Vasculitis			
subjects affected / exposed	3 / 99 (3.03%)	3 / 101 (2.97%)	
occurrences (all)	4	3	
Respiratory, thoracic and mediastinal disorders			
Pneumonia			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Lower respiratory tract infection			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Laryngeal stenosis			
subjects affected / exposed	1 / 99 (1.01%)	1 / 101 (0.99%)	
occurrences (all)	1	1	
Pneumonitis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	
occurrences (all)	1	0	

Lung adenocarcinoma subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 1	0 / 101 (0.00%) 0	
Nervous system disorders Sleep apnoea syndrome subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 2	0 / 101 (0.00%) 0	
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 1	1 / 101 (0.99%) 1	
Gastrointestinal disorders Intestinal perforation subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 1	0 / 101 (0.00%) 0	
Renal and urinary disorders Renal impairment subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 1	0 / 101 (0.00%) 0	
Infections and infestations Pneumonia subjects affected / exposed occurrences (all)	2 / 99 (2.02%) 2	3 / 101 (2.97%) 4	
Respiratory tract infection subjects affected / exposed occurrences (all)	2 / 99 (2.02%) 2	1 / 101 (0.99%) 1	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol?

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### Interruptions (globally)

Were there any global interruptions to the trial?

### Limitations and caveats

None reported

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