



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:

General information about the trial

Main objective of the trial:

Protection of trial subjects:

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment

Long term follow-up planned

No

Independent data monitoring committee (IDMC) involvement?

Notes:

Population of trial subjects

Subjects enrolled per country

Notes:

Subjects enrolled per age group

In utero

Preterm newborn - gestational age < 37 wk

Newborns (0-27 days)

Infants and toddlers (28 days-23 months)

Children (2-11 years)

Adolescents (12-17 years)

Adults (18-64 years)

From 65 to 84 years

85 years and over

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

TRAINING

TRAINING

End points

End points reporting groups

TRAINING

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: -

Serious adverse events	Control	Experimental	
Total subjects affected by serious adverse events			
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	
Vascular disorders			
Pulmonary embolism			
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	
Deep vein thrombosis			
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	
Surgical and medical procedures			
Aortic valve replacement			
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	
Cholecystectomy			
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 %

Non-serious adverse events	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?

Interruptions (globally)

Were there any global interruptions to the trial?

Limitations and caveats

None reported

TRAINING