Clinical trial results:

Summary

EudraCT number	2009-010423-58
Trial protocol	ES FR GB DE
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	
First version publication date	
Summary attachment (see zip file)	Extended synopsis (kf5503-42-extended-synopsis--without-eudract-extract.pdf)

Trial information

Trial identification

Sponsor protocol code	

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?

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: -

Baseline characteristics

End points

End points reporting groups

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Assessment type	

Dictionary used

Dictionary name	
Dictionary version	

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