



Clinical trial results:

A multicentre, open label study to evaluate the safety and efficacy of Alendros 70 therapy administered 70mg once a week in women with postmenopausal osteoporosis

Summary

EudraCT number	2005-002342-19
Trial protocol	CZ
Global end of trial date	28 May 2008

Results information

Result version number	v1 (current)
This version publication date	16 July 2016
First version publication date	16 July 2016

Trial information

Trial identification

Sponsor protocol code	07/05/ALE/TP4
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Zentiva, a.s.
Sponsor organisation address	U Kabelovny 130, Prague 10, Czech Republic, 10237
Public contact	Tomas Hauser, MD, Zentiva, a.s., +420 267 243 451, tomas.hauser@sanofi.com
Scientific contact	Tomas Hauser, MD, Zentiva, a.s., +420 267 243 451, tomas.hauser@sanofi.com

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	28 May 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 May 2008
Global end of trial reached?	Yes
Global end of trial date	28 May 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to determine the safety profile of alendronat 70mg administered once a week in this patient population based on adverse event incidence and changes in laboratory profiles

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 December 2005
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	Czech Republic: 100
Worldwide total number of subjects	100
EEA total number of subjects	100

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)	100
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

2 centers in the Czech Republic - Osteocentrum in Hradec Kralove and Osteologicke centrum in Brno

Pre-assignment

Screening details:

inclusion criteria:

Woman in ambulatory treatment

Age up to 80 years

Postmenopausal osteoporosis

DXA criteria of osteoporosis (T score L of bone in at least 2 evaluable spondyles or with proximal femur -2.5)

Signed informed consent

Period 1

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

Blinding implementation details:

design: Multicentric, open interventional clinical trial phase IV with one arm

Arms

Arm title	Main Arm
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Arm description:

one arm: multicentric, open interventional clinical trial phase IV

Arm type	Experimental
Investigational medicinal product name	Alendros 70 mg (alendronate)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

70 mg of alendronate (1 tbl.) per week. duration: 1 year

Number of subjects in period 1	Main Arm
Started	100
Completed	75
Not completed	25
Protocol deviation	25

Baseline characteristics

Reporting groups

Reporting group title	Period
Reporting group description: -	

Reporting group values	Period	Total	
Number of subjects	100	100	
Age categorical			
women with postmenopausal osteoporosis			
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)	100	100	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
women with postmenopausal osteoporosis			
Units: years			
arithmetic mean	65.11		
standard deviation	± 7.29	-	
Gender categorical			
Units: Subjects			
Female	100	100	
Male	0	0	

End points

End points reporting groups

Reporting group title	Main Arm
Reporting group description: one arm: multicentric, open interventional clinical trial phase IV	

Primary: Safety evaluation - number of subjects affected by AEs

End point title	Safety evaluation - number of subjects affected by AEs ^[1]
End point description:	

End point type	Primary
End point timeframe: AEs from the whole 1 year study	

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: interventional CT

End point values	Main Arm			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: adverse events experienced	69			

Statistical analyses

No statistical analyses for this end point

Primary: Safety evaluation - number of AEs

End point title	Safety evaluation - number of AEs ^[2]
End point description:	

End point type	Primary
End point timeframe: the whole study	

Notes:

[2] - 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: interventional CT

End point values	Main Arm			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: number of adverse events	154			

Statistical analyses

No statistical analyses for this end point

Secondary: DXA loin value

End point title	DXA loin value
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End point description:

End point type	Secondary
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End point timeframe:

the whole study

End point values	Main Arm			
Subject group type	Reporting group			
Number of subjects analysed	75			
Units: g/cm ²				
arithmetic mean (standard deviation)	0.74 (± 0.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: DXA femur value

End point title	DXA femur value
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End point description:

End point type	Secondary
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End point timeframe:

the whole study

End point values	Main Arm			
Subject group type	Reporting group			
Number of subjects analysed	75			
Units: g/cm ²				
arithmetic mean (standard deviation)	0.74 (± 0.1)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:
the whole study

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	8.0
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Reporting groups

Reporting group title	Adverse events
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Reporting group description:
all the patients

Serious adverse events	Adverse events		
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 100 (10.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Vascular disorders			
bleeding from lungs			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
arterial bleeding - complication of polypectomy			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
stroke			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Quadripareisis			

subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
suspect Wegener granulomatosis			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
ovarian cystoma (gynecological operation)			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
gynecological bleeding			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
planned operation of gallbladder (cholecystectomy)			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
planned surgery - parathyroid adenoma			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
total hip replacement			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
extraction of metal from elbow			

subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
total knee replacement			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
rehabilitation therapy			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
acute appendicitis			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
appendectomy			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Adverse events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	59 / 100 (59.00%)		
General disorders and administration site conditions			
154 non-adverse events	Additional description: there were 154 non-serious adverse events within the study		
subjects affected / exposed	59 / 100 (59.00%)		
occurrences (all)	154		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported