



Clinical trial results:

Wirkung von Oxcarbazepin (Trileptal) auf den Kortikosteroid-Metabolismus - Pilotstudie

Summary

EudraCT number	2007-003913-15
Trial protocol	AT
Global end of trial date	31 December 2009

Results information

Result version number	v1 (current)
This version publication date	13 December 2021
First version publication date	13 December 2021

Trial information

Trial identification

Sponsor protocol code	ANTRAG01
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Innsbruck
Sponsor organisation address	Christoph-Probst-Platz 1, Innrain 52, Innsbruck, Austria, 6020
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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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 December 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 December 2009
Global end of trial reached?	Yes
Global end of trial date	31 December 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Degradation products of endogenous cortisol (e.g. 6OH-Cortisol) in 24-h-urine in patients with temporal lobe epilepsy with oxcarbazepine monotherapy.

Protection of trial subjects:

All subjects had a physical health check performed.

Background therapy:

There was no background therapy.

Evidence for comparator:

There was no evidence for comparators.

Actual start date of recruitment	13 March 2008
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	Austria: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	6
Adults (18-64 years)	6
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

Patients were recruited through epilepsy outpatient clinics.

Pre-assignment

Screening details:

Exclusion criteria included any other illness apart from epilepsy or being on any other medication apart from Oxcarbazepine.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Oxcarbazepin

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Oxcarbazepin
Investigational medicinal product code	
Other name	Trileptal
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were routinely treated with Oxcarbazepin (Dose between 900 and 1500 mg/day or 16 and 21 mg/kg/day)

Arm title	Control
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Arm description: -

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Oxcarbazepin	Control
Started	6	6
Completed	6	6

Baseline characteristics

Reporting groups

Reporting group title	Oxcarbazepin
Reporting group description: -	
Reporting group title	Control
Reporting group description: -	

Reporting group values	Oxcarbazepin	Control	Total
Number of subjects	6	6	12
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)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	6	0	6
Adults (18-64 years)	0	6	6
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	15.13	20.27	
standard deviation	± 0.44	± 4.21	-
Gender categorical Units: Subjects			
Female	0	0	0
Male	6	6	12

End points

End points reporting groups

Reporting group title	Oxcarbazepin
Reporting group description: -	
Reporting group title	Control
Reporting group description: -	

Primary: 6-OHF/F

End point title	6-OHF/F
End point description:	GC-MS measured 24-h urinary excretion of C21 and C19 steroid metabolites. To assess the CYP3A4 elimination pathway, 6-OHF (6 β -hydroxycortisol) was determined, as well as the quantified relation to the normal 17-hydroxysteroid elimination pathway using the ratio 6-OHF/F (F, cortisol).
End point type	Primary
End point timeframe:	
24-h urine collection	

End point values	Oxcarbazepin	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: $\mu\text{g/day}$				
arithmetic mean (standard deviation)	4.67 ($\pm$ 1.25)	2.32 ($\pm$ 0.50)		

Statistical analyses

Statistical analysis title	6-OHF/F
Comparison groups	Oxcarbazepin v Control
Number of subjects included in analysis	12
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.001 ^[1]
Method	t-test, 2-sided

Notes:

[1] - Unadjusted result; age-adjusted result (ANCOVA): $p < 0.05$.

Primary: 6-OHF/(THF+a-THF+THE)

End point title	6-OHF/(THF+a-THF+THE)
End point description:	GC-MS measured 24-h urinary excretion of C21 and C19 steroid metabolites. To assess the CYP3A4 elimination pathway, 6-OHF (6 β -hydroxycortisol) was determined, as well as the quantified relation to the normal 17-hydroxysteroid elimination pathway using the ratio 6-OHF/(THF + a-THF + THE). (THF, tetrahydrocortisol; a-THF, allo(5 α) THF; THE, tetrahydrocortisone).

End point type	Primary
End point timeframe:	
24-h urine collection	

End point values	Oxcarbazepin	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: µg/day				
arithmetic mean (standard deviation)	0.07 (± 0.03)	0.03 (± 0.01)		

Statistical analyses

Statistical analysis title	6-OHF/(THF+a-THF+ THE)
Comparison groups	Oxcarbazepin v Control
Number of subjects included in analysis	12
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.02 [2]
Method	t-test, 2-sided

Notes:

[2] - Unadjusted result; age-adjusted result (ANCOVA): p<0.05.

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

13.03.2008-31.12.2009

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	4.0
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Reporting groups

Reporting group title	Oxcarbazepin
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Reporting group description: -

Reporting group title	Control
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Reporting group description: -

Serious adverse events	Oxcarbazepin	Control	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Oxcarbazepin	Control	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: As only blood and urine were collected in this trial, no AEs and SAEs were observed.

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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/2051596>