Clinical trial results:
Effect of atypical antipsychotics on gene expression in soft tissues of healthy subjects. A placebo controlled randomised pilot study.

Summary

EudraCT number	2009-011097-15
Trial protocol	AT
Global end of trial date	04 March 2011

Results information

Result version number	v1 (current)
This version publication date	21 September 2019
First version publication date	21 September 2019

Trial information

Trial identification

Sponsor protocol code	OLA_ZIPRA

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Vienna
Sponsor organisation address	Währinger Gürtel 18-20, Wien, Austria, 1090
Public contact	Office of the Dep. of Clinical Pharmacology, Department of Clinical Pharmacology, +431 4040029810, klin-pharmakologie@meduniwien.ac.at
Scientific contact	Office of the Dep. of Clinical Pharmacology, Department of Clinical Pharmacology, +431 4040029810, klin-pharmakologie@meduniwien.ac.at

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	04 March 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 March 2011
Global end of trial reached?	Yes
Global end of trial date	04 March 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Differences in the soft tissue gene expression profile after administration of olanzapine or ziprasidone after single and multiple dose administration.

Protection of trial subjects:

During the period of study days subjects will be observed by a physician or an experienced nurse.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 July 2010
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: 17
Worldwide total number of subjects	17
EEA total number of subjects	17

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)	17
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment by using data base of the Clinical Pharmacology

Pre-assignment

Screening details:

Information of subject, checking of In -and exclusion criteria, investigations according to study protocol

Pre-assignment period milestones

Number of subjects started	17
Number of subjects completed	

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

In the morning of the first study day, volunteers were allocated to groups A, B or C based on a block randomization schedule.
Medication and placebo was labeled and blinded at the local pharmacy.

Arms

Are arms mutually exclusive?	Yes
Arm title	Group A

Arm description:

Group A: Administration of ZYPREXA® containing 10 mg of olanzapine once daily and placebo once daily

Arm type	Active comparator
Investigational medicinal product name	Zyprexa
Investigational medicinal product code	N05AH03
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administration of ZYPREXA® containing 10 mg of olanzapine once daily and placebo once daily

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

•Group A: Administration of ZYPREXA® containing 10 mg of olanzapine once daily and placebo once daily

Arm title	Group B

Arm description:

Group B: Administration of ZELDOX® containing 40 mg of ziprasidone twice daily

Arm type	Active comparator

Investigational medicinal product name	Zeldox
Investigational medicinal product code	N05AE04
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Group B: Administration of ZELDOX® containing 40 mg of ziprasidone twice daily

Arm title	Group C

Arm description:

Group C: Administration of placebo twice daily

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

Dosage and administration details:

Group C: Administration of placebo twice daily

Number of subjects in period 1	Group A	Group B	Group C
Started	7	6	4
Completed	6	6	4
Not completed	1	0	0
Physician decision	1	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Group A
Reporting group description:	
Group A: Administration of ZYPREXA® containing 10 mg of olanzapine once daily and placebo once daily	
Reporting group title	Group B
Reporting group description:	
Group B: Administration of ZELDOX® containing 40 mg of ziprasidone twice daily	
Reporting group title	Group C
Reporting group description:	
Group C: Administration of placebo twice daily	

Reporting group values	Group A	Group B	Group C
Number of subjects	7	6	4
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)	0	0	0
Adults (18-64 years)	7	6	4
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical			
Male subjects			
Units: Subjects			
Female	0	0	0
Male	7	6	4

Reporting group values	Total		
Number of subjects	17		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	17		
From 65-84 years	0		
85 years and over	0		

Gender categorical			
Male subjects			
Units: Subjects			
Female	0		
Male	17		

End points

End points reporting groups

Reporting group title	Group A
Reporting group description:	
Group A: Administration of ZYPREXA® containing 10 mg of olanzapine once daily and placebo once daily	
Reporting group title	Group B
Reporting group description:	
Group B: Administration of ZELDOX® containing 40 mg of ziprasidone twice daily	
Reporting group title	Group C
Reporting group description:	
Group C: Administration of placebo twice daily	

Primary: Differences in the soft tissue gene expression profile after administration of olanzapine or ziprasidone after single and multiple dose administration.

End point title	Differences in the soft tissue gene expression profile after administration of olanzapine or ziprasidone after single and multiple dose administration.
End point description:	
End point type	Primary
End point timeframe:	
5/8 hours after medication	

End point values	Group A	Group B	Group C	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	6	4	
Units: Other	6	6	4	

Statistical analyses

Statistical analysis title	End point statistic
Comparison groups	Group A v Group B v Group C
Number of subjects included in analysis	16
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0001
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 19.07.2010-04.03.2011	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0
Reporting groups	
Reporting group title	Adverse Events

Reporting group description: -

Serious adverse events	Adverse Events		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 17 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	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	14 / 17 (82.35%)		
Investigations			
Asat			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Vascular disorders			
Hematoma at biopsy side			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Cephalgia			

subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	2		
Orthostatic collapse			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Akathisia			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	5		
Photophobia			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
General disorders and administration site conditions			
Tiredness			
subjects affected / exposed	7 / 17 (41.18%)		
occurrences (all)	14		
Increased appetite			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Eye disorders			
Tired eyes			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	2		
Inability to open eyes			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
muscle soreness			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Pain left thigh			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Infections and infestations			
Rhinitis			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		

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