Clinical trial results:
Proof of effectiveness of Pascoflair using qantitative measurement of electric brain activity during examination stress in 40 subjects suffering from test anxiety.
A double-blind, randomized, placebo-controlled, 2-armed, Phase IV study in parallel design.

Summary

EudraCT number	2014-003369-50
Trial protocol	DE
Global end of trial date	20 August 2015

Results information

Result version number	v1 (current)
This version publication date	28 April 2022
First version publication date	28 April 2022
Summary attachment (see zip file)	Dimpfel et al. 2016 (Dimpfel-PharmacolPharmacy-2016-Proof-of-effectiveness-Pascoflair-ExamAnxiety-EEG.pdf) Summary for German Authorities (Summary for German Authorities-20160429.pdf)

Trial information

Trial identification

Sponsor protocol code	200S14PF

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Pascoe pharmazeutische Präparate
Sponsor organisation address	Schiffenberger Weg 55, Giessen, Germany, 35394
Public contact	Klinische Forschung H. Michels, PASCOE pharmazeutische Präparate GmbH, 0049 641-796-0958, holger.michels@pascoe.de
Scientific contact	Klinische Forschung H. Michels, PASCOE pharmazeutische Präparate GmbH, 6417960963 641-7960-958, holger.michels@pascoe.de

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	18 March 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 August 2015
Global end of trial reached?	Yes
Global end of trial date	20 August 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Anxiolytic effects of PASCOFLAIR® shall be tested in subjects suffering from test anxiety after single intake by aid of a newly developed, validated method consisting of a combination of eye tracking (following glances) with neurocode tracking (quantitative EEG with a time resolution of 364 ms).

Protection of trial subjects:

The only measure in this trial with a potential risk for the participants was blood sampling, where e.g. pain, bruises, hematoma, injury of nerves or infections may occur. No adverse events due to the blood sampling occured. Further risks due to the trial design or trial measures were not expected.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 April 2015
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	Germany: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	40

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Germany: May 2015 - Aug 2015: 40 subjects were randomized and received treatment (20x verum and 20x placebo)

Pre-assignment

Screening details:

During recruitment 9 people dropped out before randomized: 7 people "were no longer interested in or had no time for participating in the study" and 2 people were excluded due to "taking medications (exclusion criterion)"

Period 1

Period 1 title	Treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Arms

Are arms mutually exclusive?	Yes
Arm title	Verum

Arm description:

subject received 2 tbl once

Arm type	Experimental
Investigational medicinal product name	PASCOFLAIR®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

single dose of 2 tbl

Arm title	Placebo

Arm description:

subject received 2 tbl once

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

Dosage and administration details:

single dose of 2 tbl

Number of subjects in period 1	Verum	Placebo
Started	20	20
Completed	20	20

Baseline characteristics

Reporting groups

Reporting group title	Treatment (overall period)

Reporting group description: -

Reporting group values	Treatment (overall period)	Total	
Number of subjects	40	40	
Age categorical			
Adults (18-64 years)			
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)	40	40	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Age - total			
Units: years			
arithmetic mean	25.75		
standard deviation	± 5.94	-	
Gender categorical			
Units: Subjects			
Female	23	23	
Male	17	17	

End points

End points reporting groups	
Reporting group title	Verum
Reporting group description: subject received 2 tbl once	
Reporting group title	Placebo
Reporting group description: subject received 2 tbl once	

Primary: Effect of Placebo or Verum on spectral beta1 power	
End point title	Effect of Placebo or Verum on spectral beta1 power
End point description: Effect of Placebo or Verum on spectral beta1 power averaged including either all or selected electrode positions given on the right upper side. Data are given as % of baseline (ref) before intake. Statistical significance (Wilcoxon-Test) in comparison to Placebo is documented by stars: *=p<0.10; **=p<0.05.	
End point type	Primary
End point timeframe: About 45 minutes after intake of study medication	

End point values	Verum	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: percent				
number (not applicable)	20	20		

Attachments (see zip file)	verum vs. placebo beta1/verum vs. placebo beta1.pdf

Statistical analyses

Statistical analysis title	Wilcoxon test
Statistical analysis description: For explorative statistical evaluation the nonparametric Wilcoxon test was used.	
Comparison groups	Placebo v Verum
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05 [1]
Method	Wilcoxon (Mann-Whitney)

Notes:

[1] - For statistical significance p<0.10 was also described.

Primary: Effect of Placebo or Verum on spectral beta2 power

End point title	Effect of Placebo or Verum on spectral beta2 power

End point description:

Effect of Placebo or Verum (PASCOFLAIR®) on spectral beta2 power
averaged including either all or selected electrode positions given on the right upper side. Data are given as
% of baseline (ref) before intake. Statistical significance (Wilcoxon-Test) in comparison to Placebo is documented by stars: *=p<0.10; **=p<0.05.

End point type	Primary

End point timeframe:

45 minutes after intake of study medication (verum or placebo)

End point values	Verum	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: percent				
number (not applicable)	20	20		

Attachments (see zip file)	verum vs. placebo beta2/verum vs. placebo beta2.pdf

Statistical analyses

Statistical analysis title	Wilcoxon test

Statistical analysis description:

For explorative statistical evaluation the nonparametric Wilcoxon test was used.

Comparison groups	Verum v Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05 [2]
Method	Wilcoxon (Mann-Whitney)

Notes:

[2] - For statistical significance p<0.10 was also described.

Secondary: Tolerability

End point title	Tolerability

End point description:

At the end of the measurements, the tolerability of verum or placebo was assessed: very good, good, moderately, poor.

End point type	Secondary

End point timeframe:

One study day for each patient

End point values	Verum	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: participants	20	20		

Attachments (see zip file)	Tolerability/Tolerability.pdf

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Overall period	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.1
Reporting groups	
Reporting group title	Verum
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	Verum	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (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	Verum	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	2 / 20 (10.00%)	
Investigations			
heart murmur	Additional description: The volunteer has been informed about her heart murmur and was invited to a further visit.		
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
increased GPT			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
increased GOT			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 April 2015	Changes in study protocol (version 2.0) Changes in ICF (version 3.0) Changes labeling study medication

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported