



Clinical trial results:

Proof of effectiveness of Pascoflair using quantitative 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 occurred. 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