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Bioequivalence study of Tobramycin PARI (T100) versus TOBI® (Novartis) in cystic fibrosis patients with bronchopulmonary chronic Pseudomonas aeruginosa (PA) infection

Submission date
03/02/2011

Recruitment status
No longer recruiting

Registration date
12/04/2011

Overall study status
Completed

Last Edited
29/06/2015

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
12012.101

Study information

Scientific Title

A comparative, randomised, two period, multi-centre, cross-over 14 weeks bioequivalence study of Tobramycin PARI (T100) versus TOBI® (Novartis) in cystic fibrosis patients with bronchopulmonary chronic Pseudomonas aeruginosa (PA) infection

Acronym
T100

Study objectives
It is postulated that the pharmacokinetics of T100 170 mg delivered with the Pari eFlow® after 4 weeks treatment is bioequivalent with the pharmacokinetics of TOBI® 300 mg delivered with the PARI LC® PLUS

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethics Committee of the Institute of Mother and Child in Warsaw, 21/01/2011, ref: 05/2011

Study design
Comparative randomised two period multi-centre cross-over bioequivalence study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cystic fibrosis patients with bronchopulmonary chronic Pseudomonas aeruginosa infection

Interventions
Each patient will be randomised in a (1:1) ratio to receive either 2 x 170 mg/day T100/ Pari eFlow® or 2 x 300 mg/day TOBI®/PARI LC® PLUS.

After treatment phase 1 all patients switch to the conversed treatment group. Each treatment phase will last for 28 days.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tobramycin

Primary outcome(s)
Comparison of mean plasma tobramycin AUC (0-12h) of T100 170 mg nebulised via Pari eFlow® and the registered TOBI® 300 mg nebulised via PARI LC® PLUS

Key secondary outcome(s))
Comparison of tobramycin peak plasma levels (Cmax plasma) of T100 nebulised via Pari eFlow® and the registered TOBI® nebulised via PARI LC® PLUS

Completion date
30/08/2011

Eligibility

Key inclusion criteria
1. Signed by patient (or appropriate legal representative) the written informed consent including data protection agreement after the nature of the study has been fully explained prior to any screening procedure
2. Patient is a male or female and at least 4 years of age at the time of screening
3. Patient's diagnosis of cystic fibrosis (CF) was confirmed by one or more specific clinical features consistent with CF and elevated chloride concentration in the sweat is greater than 60 mEq/l (by quantitative pilocarpine iontophoresis test - QPIT)
4. Presence of disease associated CF transmembrane conductance regulator (CFTR) mutations in both alleles
5. Patient has adequate pulmonary function at screening defined as:
5.1. Forced expiratory volume in one second (FEV1) between at least 25% and less or equal to 85% of normal predicted values for age, sex and height based on Knudson criteria and peripheral artery haemoglobin oxygen saturation (SaO2) of at least 88% at rest measured by pulse oximetry on room air
6. Patient has a positive culture for PA at screening (Visit 1)
6.1. Patient should have PA isolated from sputum only if patient do not have a known history of positive PA culture within the last 2 months
7. Patient is clinically stable at screening (no change in FEV1 greater than 20% within one month prior to screening visit)
8. Patient is able to comply with all protocol requirements (e.g. able to produce sputum and perform pulmonary function tests)
9. Sexually active women of childbearing potential and sexually active men will use a highly effective method of contraception throughout the IMP treatment period
10. Females of childbearing potential have a negative serum pregnancy test (within 7 days before visit 2/randomisation)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria

1. Use of investigational medications within 30 days before study entry or during the trial
2. Inability to handle the study inhalers to inhale the test preparations
3. Patient has a known local or systemic hypersensitivity or adverse reaction to inhaled aminoglycosides or systemic aminoglycosides
4. Administration of anti-pseudomonas aminoglycoside antibiotics are not allowed within 30 days before first administration of IMP. Macrolide are permitted, provided that they are taken as a maintenance therapy for at least 6 weeks before entering the trial. Other antibiotics are not allowed within 7 days before first administration of IMP
5. Patient with haemoptysis at any time within 4 weeks prior to screening (Visit 1)
6. FEV1 less than 25% predicted
7. Patient has a positive sputum or deep throat cough culture or bronchoalveolar lavage (BAL) with Burkholderia cepacia (B cepacia) at screening (visit 1) and/or a history of positive culture yielding B cepacia within 1 year prior to screening
8. Presence of allergic bronchopulmonary aspergillosis (ABPA)
9. Patient experienced severe respiratory infection within one month prior to screening (visit 1) which requires hospitalisation or treatment with intravenous (i.v.) antibiotics
10. Elevated serum creatinine greater than 1.2 mg/dl or blood urine nitrogen (BUN) 20 mg/dl or proteinuria of grade 2plus or greater
11. Significant liver disease -greater than 2x upper standard limits and no thrombocytopenia or clinical active disease
12. Patients with auditory or/and vestibular dysfunctions
13. Patient has a history of lung transplantation
14. Patient has a co-existing medical condition or abnormality that would compromise the participant's safety or the quality of the study data, in the opinion of the investigator
15. Active drug and alcohol abuse or psychiatric disease

Date of first enrolment
15/03/2011

Date of final enrolment
30/08/2011

Locations

Countries of recruitment
Poland

Study participating centre
Instytut Matki i Dziecka
Warszawa
Poland
01-211

Sponsor information

Organisation
PARI Pharma GmbH (Germany)

ROR
https://ror.org/011pcrd91

Funder(s)

Funder type
Industry

Funder Name
PARI Pharma GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes