Clinical trial results:
Myfortic (enteric-coated mycophenolate sodium) for the treatment of non-infectous intermediate uveitis – a prospective, controlled randomized multicenter trial

Summary

EudraCT number	2009-009998-10
Trial protocol	DE
Global end of trial date	02 October 2015

Results information

Result version number	v1 (current)
This version publication date	02 December 2021
First version publication date	02 December 2021
Summary attachment (see zip file)	Statistical analysis report (APPENDIX 16.5 Statistical Analysis Report.pdf) Safety report_Adverse events (APPENDIX 16.6 Safety Report 2016-06-30.pdf)

Trial information

Trial identification

Sponsor protocol code	MYCUV-IIT02

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Centre for Ophthalmology, University of Tübingen
Sponsor organisation address	Schleichstraße 12, Tübingen, Germany, 72076
Public contact	Dr. med. Bodo Wahlländer, Centre for Ophthalmology, University of Tübingen, +49 0911-27312633, christoph.deuter@med.uni-tuebingen.de
Scientific contact	Dr. med. Christoph Deuter, Centre for Ophthalmology, University of Tübingen, +49 0911-27312633, christoph.deuter@med.uni-tuebingen.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	15 October 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 October 2015
Global end of trial reached?	Yes
Global end of trial date	02 October 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this clinical trial to evaluate the efficacy, safety and tolerability of enteric-coated mycophenolate sodium in combination with low-dose corticosteroids compared to a monotherapy with low-dose corticosteroids in subjects with non-infectious intermediate uveitis.

Protection of trial subjects:

This study was reviewed and approved by the ethics committees of the participating study centers as well as by the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) in Bonn. The leading ethics committee for this trial was the Clinical Ethics Committee at the University Hospital Tübingen. This study was conducted in accordance with the tenets of the Declaration of Helsinki. All patients received a written patient information. Patients were given sufficient time for consideration and opportunity to ask questions. Finally, written informed consent was obtained at the screening visit, before any studyrelated procedures were performed. Patients received a copy of the signed informed consent form.

Background therapy:

The following concomitant treatments for uveitis were allowed during the study:
• Oral acetazolamide (e.g. Diamox®) in a dose up to 250 mg BID. Dose had to be stable for at least 2 weeks prior to screening. Tapering should be started at visit 4 (month 3) at the discretion of the investigator.
• Topical prednisolone, topical non-steroidal anti-inflammatory drugs. Dose had to be stable for at least 2 weeks prior to screening. Tapering should be started at visit 4 (month 3) at the discretion of the investigator.
• Mydriatics

Evidence for comparator: -

Actual start date of recruitment	27 April 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 47
Worldwide total number of subjects	47
EEA total number of subjects	47

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)	47
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Centre for Ophthalmology, University Hospital Tübingen,
Germany (PD Dr. Christoph Deuter)
• Eye Clinic, Klinikum Chemnitz gGmbH, Chemnitz, Germany
(Prof. Dr. Katrin Engelmann)
• Department of Ophthalmology, St. Franziskus Hospital, Münster,
Germany (Prof. Dr. Arnd Heiligenhaus)
• Department of Ophthalmology, Technical University of Munich,

Pre-assignment

Screening details:

Unfortunately, the projected number of 144 patients could not be reached and the recruitment had to be stopped prematurely after screening of 47 patients and randomisation of 44 patients
at eight sites.

Period 1

Period 1 title	Baseline period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

It was an open-label study. Patients who were allocated to the control group and who developed the first relapse within 6 months after randomisation changed to the 'crossover group'.

Arms

Are arms mutually exclusive?	Yes
Arm title	Prednisolone + Myfortic

Arm description:

Treatment group: Tapering of oral prednisolone continued over approximately 3 months to a maintenance dose of 5 mg/day plus EC-MPS (Myfortic; Novartis, Basel, Switzerland) at
a dose of 720 mg/day during the first week and 1440 mg/day from week 2 onwards.

Arm type	Experimental
Investigational medicinal product name	Prednisolone
Investigational medicinal product code	
Other name	Decortin H®
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Tapering of oral prednisolone continued over approximately 3 months to a maintenance dose of 5 mg/day

Investigational medicinal product name	Myfortic
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Tapering of oral prednisolone continued over approximately 3 months to a maintenance dose of 5 mg/day plus EC-MPS (Myfortic; Novartis, Basel, Switzerland) at
a dose of 720 mg/day during the first week and 1440 mg/day from week 2 onwards.

Arm title	Control arm

Arm description:

Control group: Tapering of oral prednisolone continued over approximately 3 months to a maintenance

dose of
5 mg/day.

Arm type	Active comparator
Investigational medicinal product name	Prednisolone
Investigational medicinal product code	
Other name	Decortin H
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Tapering of oral prednisolone continued over approximately 3 months to a maintenance dose of 5 mg/day.

Number of subjects in period 1[1]	Prednisolone + Myfortic	Control arm
Started	22	19
Completed	22	19

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 47 patients were enrolled and 41 were evaluable (22 in the treatment group and 19 in the control group)

Baseline characteristics

Reporting groups

Reporting group title	Baseline period

Reporting group description: -

Reporting group values	Baseline period	Total	
Number of subjects	41	41	
Age categorical			
The mean age was 47.2 years (18.6-82.7 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)	41	41	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Mean age was 47.2 years (18.6–82.7 years).			
Units: years			
geometric mean	47.2		
standard deviation	± 16.7	-	
Gender categorical			
Units: Subjects			
Female	25	25	
Male	16	16	

Subject analysis sets

Subject analysis set title	Final analysis
Subject analysis set type	Full analysis

Subject analysis set description:

Intent-to-treat population and safety population were defined as all subjects who received at least one dose of prednisolone or
EC-MPS and did have at least one post-baseline assessment or at least one post-therapy safety assessment, respectively.

Reporting group values	Final analysis		
Number of subjects	41		
Age categorical			
The mean age was 47.2 years (18.6-82.7 years)			
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)	41		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Mean age was 47.2 years (18.6–82.7 years).			
Units: years			
geometric mean	47.2		
standard deviation	± 16.7		
Gender categorical			
Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	Prednisolone + Myfortic

Reporting group description:

Treatment group: Tapering of oral prednisolone continued over approximately 3 months to a maintenance dose of 5 mg/day plus EC-MPS (Myfortic; Novartis, Basel, Switzerland) at a dose of 720 mg/day during the first week and 1440 mg/day from week 2 onwards.

Reporting group title	Control arm

Reporting group description:

Control group: Tapering of oral prednisolone continued over approximately 3 months to a maintenance dose of 5 mg/day.

Subject analysis set title	Final analysis
Subject analysis set type	Full analysis

Subject analysis set description:

Intent-to-treat population and safety population were defined as all subjects who received at least one dose of prednisolone or EC-MPS and did have at least one post-baseline assessment or at least one post-therapy safety assessment, respectively.

Primary: time from study entry to the first relapse

End point title	time from study entry to the first relapse[1]

End point description:

To evaluate whether a EC-MPS based regimen will be able to reduce the probability of a relapse compared to steroid therapy alone. The primary endpoint of the study is defined as the time from study entry to the first relapse.
Definition of relapse:
• Deterioration of best corrected visual acuity (BCVA) ≥ 3 lines compared to best BCVA from baseline.
At least 2-step increase of vitreous haze compared to lowest grade of vitreous haze from baseline or increase from 3+ to 4+.
• At least 2-step increase of anterior chamber cells compared to lowest grade of anterior chamber cells from baseline or increase from 3+ to 4+.
• New onset or worsening of preexisting cystoid macular edema, proven by Optical Coherence Tomography (OCT)
• New onset or worsening of retinal vasculitis (sheating and/or leakage of retinal vessels), proven by fluorescein angiography (FA).

End point type	Primary

End point timeframe:

Until first relapse

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis can be found in the attached documents

End point values	Prednisolone + Myfortic	Control arm	Final analysis	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	22	19	24	
Units: months	15	3	24	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: The whole duration of the trial	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 1 %

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: Safety Report can be found in the attached documents

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/28903965