Clinical trial results:
A Pilot Study Evaluating the Effect of Intravitreal Fluocinolone Acetonide (0.19mg) in Patients with Retinitis Pigmentosa

Summary

EudraCT number	2016-002523-28
Trial protocol	GB
Global end of trial date	20 October 2016

Results information

Result version number	v1 (current)
This version publication date	14 March 2019
First version publication date	14 March 2019
Summary attachment (see zip file)	Suspended - no results (SUSPENDED.pdf)

Trial information

Trial identification

Sponsor protocol code	KHAK1001

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Moorfields Eye Hospital NHS Foundation Trust
Sponsor organisation address	162 City Road, London, United Kingdom, EC1V 2PD
Public contact	Natasha Ajraam, R&D, Moorfields Eye Hospital, 020 72533411, natasha.ajraam@moorfields.nhs.uk
Scientific contact	Natasha Ajraam, R&D, Moorfields Eye Hospital, 020 72533411, natasha.ajraam@moorfields.nhs.uk
Sponsor organisation name	Moorfields Eye Hospital NHS Foundation Trust
Sponsor organisation address	162 City Road, London, United Kingdom, EC1V 2PD
Public contact	Natasha Ajram , Natasha Ajram Moorfields Eye Hospital, 162 City Road, London, 020 72533411, moorfields.resadmin@nhs.net
Scientific contact	Natasha Ajram , Natasha Ajram Moorfields Eye Hospital, 162 City Road, London, 020 72533411, moorfields.resadmin@nhs.net

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	20 October 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 October 2016
Global end of trial reached?	Yes
Global end of trial date	20 October 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

1. To describe the anatomical and functional changes occurring in treated and control eyes over a 36-month period.

Technical outcome measures =
OCT: (1) Change in area of ellipsoid zone integrity (mm2) at the macula. (2) Change in outer retinal thickness across the macula. (3) Change in subfoveal choroidal thickness (mm).
FAF: (1) Change in area demonstrating “loss of AF” on standard 55° macula centred image (mm2). (2) Area within the ring of hyperautofluorescence (mm2).
Visual Field: Change in size of V4e isopter area.

Protection of trial subjects:

No patients recruited - study was suspended prior to any recruitment.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2016
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	United Kingdom: 1
Worldwide total number of subjects	1
EEA total number of subjects	1

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)	1
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No recruitment - study was suspended prior to any recruitment. 1 patient entered as recruited to satisfy data entry reporting for database.

Pre-assignment

Screening details:

No patients screened.

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	immunosuppressive therapeutic

Arm description:

Administration of Iluvien

Arm type	Implant for intravitreal injection
Investigational medicinal product name	Illuvin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Intravitreal implant in applicator
Routes of administration	Ocular use

Dosage and administration details:

Synthetic corticosteroid derivative. Fluocinolone acetonide is a white or almost white, microcrystalline powder, practically insoluble in water, soluble in methanol, ethanol, chloroform and acetone, and sparingly soluble in ether.

Number of subjects in period 1	immunosuppressive therapeutic
Started	1
Completed	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	immunosuppressive therapeutic
Reporting group description:	
Administration of Iluvien	

Primary: anatomical and functional changes occurring in treated and control eyes

End point title	anatomical and functional changes occurring in treated and control eyes[1]
End point description:	
End point type	Primary
End point timeframe:	
36 months	

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: none specified as trial was suspended - no patients recruited.

End point values	immunosuppressive therapeutic			
Subject group type	Reporting group			
Number of subjects analysed	1[2]			
Units: months				
number (not applicable)	1			

Notes:

[2] - no patients recruited

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: as per protocol	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 5 %

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: none specified as trial was suspended - no patients recruited.

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