Clinical trial results:
Intravitreal Ranibizumab (Lucentis) Therapy in Patients with Diabetic Ischaemic Macular Oedema (DIME)

Summary

EudraCT number	2013-000031-27
Trial protocol	GB
Global end of trial date	04 February 2014

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)	Premature end of study - no results (cover letter to MHRA-declaration of end of study.pdf)

Trial information

Trial identification

Sponsor protocol code	MICM1008

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 Research Facilitator, Moorfields Eye Hospital NHS Foundation Trust, 020 72533411, natasha.ajraam@moorfields.nhs.uk
Scientific contact	Natasha Ajraam Research Facilitator, Moorfields Eye Hospital NHS Foundation Trust, 020 72533411, natasha.ajraam@moorfields.nhs.uk

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	04 February 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 February 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Is the use of Lucentis therapy in patients with Diabetic Ischaemic Macular Oedema (DIME) safe?

Protection of trial subjects:

No patients were recruited in this study. 1 patient entered to allow completion of the record, however no patients were recruited.

Background therapy:

0

Evidence for comparator:

0

Actual start date of recruitment	01 February 2013
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 abandoned.

Pre-assignment

Screening details:

No screening, study abandoned.

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	Injection

Arm description:

phase III/IV non-randomised, prospective case series

Arm type	injection
Investigational medicinal product name	Lucentis therapy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Ocular use

Dosage and administration details:

Lucentis injections (0.5mg) will be administered monthly for 3 months then according to clinical need for a total of 12 months of follow-up. A minimum of 5 intravitreal Lucentis injections will be administered prior to a decision being taken that there is a lack of clinical response.

Number of subjects in period 1	Injection
Started	1
Completed	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	Injection
Reporting group description: phase III/IV non-randomised, prospective case series	
Subject analysis set title	Safety data
Subject analysis set type	Per protocol
Subject analysis set description: 1. Macular perfusion (FAZ greatest linear dimension (GLD) and degree of perifoveal capillary loss)	

Primary: Macular perfusion (FAZ greatest linear dimension (GLD) and degree of perifoveal capillary loss)

End point title	Macular perfusion (FAZ greatest linear dimension (GLD) and degree of perifoveal capillary loss)[1]
End point description:	
End point type	Primary
End point timeframe: 30 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: no patients were recruited as the study was abandoned.

End point values	Injection			
Subject group type	Reporting group			
Number of subjects analysed	1[2]			
Units: FAZ greatest linear dimension (GLD)				
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: no patients were recruited as the study was abandoned.

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