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An observational study following patients newly diagnosed with neovascular or 'wet' Age-related Macular Degeneration (AMD) looking at the changes within the eye both before and after treatment with anti-VEGF injection therapy

Submission date
04/04/2017

Recruitment status
No longer recruiting

Registration date
10/05/2017

Overall study status
Completed

Last Edited
17/10/2023

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Wet (or neovascular) age-related macular degeneration is a condition which occurs in the macula (the centre part of the retina of the eye) which can cause irreversible sight loss if not treated quickly. It is therefore important to detect it early so that treatment can be started as soon as possible to help prevent loss of sight. Patients with wet AMD in one eye have an increased likelihood of developing the condition in their other eye. The EDNA study is recruiting patients newly diagnosed with wet AMD to collect information on how good various tests are in detecting the first signs of development of wet AMD. This study (FASBAT) is an extension to the EDNA study. The aim of this study is to look at the changes within the eye before and after treatment for patients who have been recently diagnosed with wet AMD.

Who can participate?
Patients aged 50 and over with newly diagnosed wet AMD with one eye affected and one eye unaffected, who are about to start or have recently started treatment in the affected eye, and already participating in the EDNA study

What does the study involve?
The EDNA and FASBAT studies observe the same group of patients, monitoring their disease progression. The patients leave the EDNA study when wet AMD is detected in their other eye. Participants are then monitored for a further two years as part of the FASBAT study. Information collected at routine eye clinic visits for assessment and treatment is analysed to look at changes in both eyes. If participants develop wet AMD in their other eye during the study the changes that have occurred in both of the eyes over time are compared, to look at any effects of treatment on vision and quality of life.

What are the possible benefits and risks of participating?
Participating may not directly help patients but the information obtained from the study may help to improve the treatment of people with wet AMD in the future. This is a study of routine clinical care therefore there should be no risks or disadvantages to patients taking part. There is an extremely small risk that patients may have a serious allergy to the dye used in the eye examination at the end of the study. However, the risk of this occurring is minimal.

Where is the study run from?
York Teaching Hospital NHS Foundation Trust and 20 other NHS trusts (UK)

When is the study starting and how long is it expected to run for?
November 2015 to February 2022 (updated 23/09/2022, previously: February 2019; updated 19 /07/2019, previously: April 2022)

Who is funding the study?
Novartis Pharmaceuticals UK Limited (UK)

Who is the main contact?
1. Miss Mia Porteous (public)
mia.porteous@york.nhs.uk
2. Mr Richard Gale (scientific)

Contact information

Type(s)
Public

Contact name
Miss Mia Porteous

Contact details
York Teaching Hospitals NHS Foundation Trust
Wigginton Road
York
United Kingdom
YO31 8HE
+44 (0)1904 725129
mia.porteous@york.nhs.uk

Type(s)
Scientific

Contact name
Mr Richard Gale

Contact details
York Teaching Hospital NHS Foundation Trust
Wigginton Road

York
United Kingdom
YO31 8HE

Additional identifiers

Integrated Research Application System (IRAS)
197731

Protocol serial number
IRAS 197731

Study information

Scientific Title
Observing fibrosis, macular atrophy and sub retinal highly reflective material before and after intervention with anti-VEGF treatment - an extension to the EDNA study

Acronym
FASBAT

Study objectives
Age-related macular degeneration (AMD) is the commonest cause of blindness in the retired western world population. Anti-Vascular Endothelial Growth Factor (Anti-VEGF) injectable treatment has had a significant impact on reducing the levels of blindness and restoring part of the visual loss experienced by individuals who have the less common, but more aggressive, 'wet' form of Age-related Macular Degeneration (AMD) or neovascular AMD (nvAMD).

However, scarring, tissue loss and abnormal tissue formation (fibrosis and atrophy) beneath the crucial light sensitive part of the eye, the macula, limits the visual improvement that may be achieved for a patient. The late stage characteristics of fibrosis and atrophy of the outer retina remain the key pathological element associated with severe visual loss. New treatments are being developed that reduce this scar tissue formation on the assumption that better visual outcome with treatment of wet AMD may be possible. In particular there is a need to study whether it is possible to predict this tissue formation and/or response. At present there is no long term data on the development and progression of these forms of abnormal tissue. Being able to identify these features, develop new biomarkers, document their natural history and their response to treatment will aid the development of new treatment strategies.

The FASBAT study aims to monitor the progression of abnormal tissue formation based on (i) characteristics observed in an eye before (and after) the development of wet AMD in that eye, and (ii) characteristics observed in an (as yet) unaffected eye when a patient has wet AMD in their fellow eye.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & the Humber – Leeds West Ethics Committee, 02/03/2016, ref: 16/YH/0089

Study design
Multicentre observational cohort extension to the EDNA study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Neovascular age-related macular degeneration

Interventions
FASBAT is an observational extension to the EDNA study. As such only patients who have already been consented to EDNA will be approached and consented into FASBAT if willing. Any treatment given is as part of standard care clinical practice for nvAMD patients. In addition to this participants must complete the NEI-VFQ-25 Quality of Life questionnaire at the various study milestones (up to a maximum of five questionnaires).

FASBAT will observe those patients recently diagnosed with nAMD in one eye. Patients will have commenced (or are about to commence) treatment with anti-VEGF injection therapy and be regularly monitored for disease activity in both eyes as part of routine clinical care. The study eye for both EDNA and FASBAT is the non nAMD eye. The study aims to monitor disease progression in both eyes and analyse information collected during a patients routine clinic visits.

If a patient develops nAMD in their second eye the study will compare changes that occur in both eyes over time both before and after treatment, look at the changes that develop in the initial nAMD eye following anti-VEGF injection therapy and compare this to the changes in the second eye in those patients who convert in this eye. Patients will be observed up to a maximum period of 5 years.

The principle outcome measurements will be acquired using colour fundus photography, autofluorescence, fluorescein, ICG and OCT angiography and SD OCT which are all acquired as part of routine clinical practice. Images, data obtained as part of the EDNA study and data specific to FASBAT, will be captured at the patient clinic visits that occur at EDNA baseline and as close as possible to 18 and 36 months post EDNA baseline. These are the regular EDNA study visits. If a patient converts in the second eye during this period then their involvement in EDNA concludes, they remain in FASBAT and images and data are collected during their routine clinic visits at 12 and 24 months post conversion.

There are a maximum number of 5 visits per patient depending on if/when the patient converts to nAMD in the second eye. Patients may have fewer assessments depending on the date of conversion.

For patients who do not convert assessment visits are as follows (these are both EDNA and FASBAT time points):
Baseline – 18 month – 36 month/conversion – if no conversion to nAMD the patient then exits both studies.

For patients who do convert there are a further 2 assessment visits (these are FASBAT only time points):
12 months post-conversion – 24 months post-conversion then the patient exits FASBAT.

The maximum time that a patient will be enrolled into FASBAT will be 60 months. However, many patients (those who do not develop nvAMD in their second eye) will exit the study after 36 months when the EDNA phase of the study concludes.

Intervention Type
Other

Primary outcome(s)
1. Incidence of fibrosis and sub retinal highly reflective material (SHRM) over 12 months post-conversion in the initially dry eye
2. Presence of fibrosis and SHRM over 12 months post-conversion in the initially nAMD eye
3. Rate of change of atrophy from baseline to conversion initially dry eye (based on colour photography)
4. Rate of change of atrophy (total and area distinct from CNV) from baseline to conversion in the initially nAMD eye (based on colour photography)

In both primary and secondary outcomes changes in disease activity are acquired using the following: colour fundus photography, autofluorescence, fluorescein, ICG and OCT angiography and SD OCT which are all acquired as part of routine clinical practice. Data and imaging is collected at baseline, 18 months post baseline, 36 months post baseline/conversion, 12 months post conversion and 24 months post conversion

Key secondary outcome(s))
1. Mean VA and change from baseline to conversion in both eyes (Snellen scale)
2. Mean VA and change from conversion to 12 and 24 months post conversion with 15 letters gained/lost in both eyes (Snellen scale)
3. The quantity of SHRM at baseline in the initially treated eye and at conversion in the initially dry eye (correlation)
4. The change in the quantity of SHRM from baseline in the initially nAMD eye and from conversion in the initially dry eye over the study period (correlation)
5. Rate of change of SHRM stratified with baseline quantity (small and large depending upon baseline mean area), treatment type, number of treatments, visits and regimen (to the end of the study)
6. The rate of change of SHRM in those of different angiographic subgroups, leakage, presence of haemorrhage, RPE changes, IRF, SRF, ORTs, drusen or pseudo drusen
7. The quantity of fibrosis at baseline in the initially treated eye and at conversion in the initially dry eye (correlation)
8. The change in the quantity of fibrosis from baseline in the initially nAMD eye and from conversion in the initially dry eye over the study period (correlation)
9. Rate of change of fibrosis stratified with baseline quantity (small and large depending upon baseline mean area), treatment type, number of treatments, visits and regimen (to the end of the study)
10. The rate of change of fibrosis in those of different angiographic subgroups, leakage, presence of haemorrhage, RPE changes, IRF, SRF, ORTs, drusen or pseudo drusen
11. Correlation between identification (rates) of fibrosis on Colour and OCT
12. The background rate of atrophy (total and CNV distinct) in both the initially dry and nAMD eyes

13. Rate of change of atrophy (total and area distinct from CNV) in both the dry and nAMD eyes over the course of the study (correlation)
14. Rate of change of atrophy stratified with baseline area (small and large depending upon 50% baseline mean area), hyper reflective AF categories, treatment type
15. Rate of change of atrophy in those of different angiographic subgroups, leakage, presence of haemorrhage, RPE changes, drusen or pseudo drusen
16. Correlation between the rates of atrophy during the study based upon Colour, AF and OCT
17. Rate of change of atrophy stratified with baseline area (small and large depending upon baseline mean area), treatment type
18. Correlation between the rate of change of atrophy and SHRM
19. Mean change in VA correlated with baseline presence of type and location of GA, SHRM, RPE changes, IRF, SRF, ORT's, PED, drusen, reticular pseudo drusen, haemorrhage
20. Change in QoL score correlated with change in VA, atrophy, fibrosis and SHRM

In both primary and secondary outcomes changes in disease activity are acquired using the following: colour fundus photography, autofluorescence, fluorescein, ICG and OCT angiography and SD OCT which are all acquired as part of routine clinical practice. Data and imaging is collected at baseline, 18 months post baseline, 36 months post baseline/conversion, 12 months post conversion and 24 months post conversion

Completion date
07/02/2022

Eligibility

Key inclusion criteria
1. The patient must have been enrolled into EDNA
2. Individuals aged 50 and over with newly diagnosed nvAMD with one eye affected and one eye unaffected who are about to commence or have recently commence anti-VEGF therapy in the affected eye
3. Exit from EDNA must be less than or equal to 12 months prior to enrolment into FASBAT
4. The patient must be willing to enter FASBAT and able to provide data and attend assessment clinics for a further 2 years following the exit of EDNA

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
431

Key exclusion criteria

1. nvAMD in study eye detected at baseline for the EDNA study
2. Presenting worse than 68 letters at baseline in the EDNA study
3. Retinal or media pathology in either eye that will prevent sufficient quality of imaging (in the view of the investigator)
4. Not undergoing regular monitoring in standard of care
5. FFA contraindicated

Date of first enrolment
19/04/2016

Date of final enrolment
07/05/2021

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Study participating centre
York Teaching Hospital NHS Foundation Trust
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Colchester University Hospital NHS Foundation Trust
Colchester
United Kingdom
CO4 5JL

Study participating centre
Hull and East Yorkshire Hospitals NHS Trust
Hull
United Kingdom
HU3 2JZ

Study participating centre

Leeds Teaching Hospitals NHS Foundation Trust
Leeds
United Kingdom
LS1 3EX

Study participating centre
Frimley Health NHS Foundation Trust
Frimley
United Kingdom
GU16 7UJ

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Belfast Health and Social Care Trust
Belfast
United Kingdom
BT8 8BH

Study participating centre
James Paget University Hospital NHS Foundation Trust
Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre
Buckinghamshire Healthcare NHS Trust - Stoke Mandeville Hospital
Aylesbury
United Kingdom
HP21 8AL

Study participating centre

University Hospitals Coventry and Warwickshire - Hospital of St Cross Rugby
Rugby
United Kingdom
CV22 5PX

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Harrogate and District NHS Foundation Trust
Harrogate
United Kingdom
HG2 7SX

Study participating centre
Central Manchester University Hospitals NHS Foundation Trust
Manchester
United Kingdom
M13 9WL

Study participating centre
The Hillingdon Hospitals NHS Foundation Trust
Hillingdon
United Kingdom
UB8 3NN

Study participating centre
Cardiff and Vale University Health Board
Cardiff
United Kingdom
CF24 0SZ

Study participating centre

Moorfields Eye Hospital NHS Foundation Trust
London
United Kingdom
EC1V 2PD

Study participating centre
University Hospitals Of Leicester - Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

Study participating centre
City Hospitals Sunderland NHS Foundation Trust
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Royal Liverpool University Hospital
Liverpool
United Kingdom
L7 8XP

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Sheffield
United Kingdom
S10 2JF

Study participating centre
The Royal Wolverhampton NHS Trust
Wolverhampton
United Kingdom
WV10 0QP

Sponsor information

Organisation
York Teaching Hospital NHS Foundation Trust

ROR
https://ror.org/027e4g787

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharmaceuticals UK Limited

Alternative Name(s)
Novartis UK, NOVARTIS UK LIMITED

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository (https://w3.abdn.ac.uk/hsru/FASBAT/Public/Public/index.cshtml). Requests to review datasets will be discussed and considered by the FASBAT Study Group and Chief Investigator on an individual basis.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes