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ASTIClite EBMT follow-up

Submission date 03/01/2018	**Recruitment status** Stopped	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 19/01/2018	**Overall study status** Stopped	
Last Edited 11/08/2022	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Crohn's disease is a long-term condition that causes inflammation of the lining of the digestive system. There is no cure at the moment, and current treatments only reduce symptoms, and often have intolerable side effects. In some patients, current treatments only provide temporary benefit, or they fail to respond at all. An alternative therapy is haematopoetic stem cell transplantation (HSCT). This treatment is being assessed in the ASTIClite study, and this study aims to assess the long-term safety and effectiveness of this procedure.

Who can participate?
Patients with Crohn's disease taking part in the ASTIClite study

What does the study involve?
Data collected from the point of stem cell transplant (or equivalent day 0 in the control group) are entered into a database, along with annual follow-up data for at least four years after the end of the study. This data collection takes place in standard care for all patients undergoing transplantation, but this study collects the data for all participants, regardless of whether they have had a transplant or continued on usual care.

What are the possible benefits and risks of participating?
It is not known whether HSCT offers long term benefits for patients with Crohn's disease, and this is the reason for carrying out this study. If the treatment is found to be more effective than the usual care patients receive, this will inform the treatment of future patients with Crohn's disease. By taking part in the study, participants are directly helping to do this. Participants are contacted for an annual visit with the study nurse, and are provided with their contact details so they have someone to contact with any questions or concerns. Taking part in this study may mean an additional burden of appointments at the recruiting NHS Trust, but it is likely that for most participants this burden is in line with their usual care had they not been part of a study. It is not currently known what the long term effects of HSCT are, and there is therefore the possibility of late side effects of the treatment. Participants are provided with the contact details of their local research team, their GP is informed of their participation in the study, and participants are advised to contact the study team with any questions or concerns.

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
August 2017 to May 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Lizzie Swaby

Contact information

Type(s)
Scientific

Contact name
Miss Lizzie Swaby

Contact details
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United Kingdom
S1 4DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36336

Study information

Scientific Title
Autologous Stem cell Transplantation In refractory Crohn’s disease – Low Intensity Therapy Evaluation (ASTIClite) – long-term follow up through the EBMT

Study objectives
Crohn's disease is a long term condition that causes inflammation of the lining of the digestive system. There is no cure at the moment, and current treatments only reduce symptoms, and often have intolerable side effects. In some patients, current treatments only provide temporary benefit, or fail to respond at all. An alternative therapy is haematopoetic stem cell transplantation (HSCT). This treatment is being assessed in the ASTIClite randomised controlled trial, and this study aims to assess the long term safety and efficacy of this procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester East Research Ethics Committee, 04/12/2017, ref: 17/NW/0669

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Crohn's disease

Interventions
Participants recruited to the ASTIClite RCT will be invited to take part in the EBMT follow-up study, and will sign a separate consent form. Data collected from the point of stem cell transplant (or equivalent day 0 in the control group) will be entered into the EBMT database, along with annual follow up data for at least four years after the end of the RCT. This data collection takes place in standard care for all patients undergoing transplantation, but this research will collect the data for all participants, regardless of whether they have had a transplant, or continued on usual care.

Intervention Type
Other

Primary outcome measure
Documentation of adverse events; Timepoint(s): At each annual follow up visit (four to seven years)

Secondary outcome measures
Participants are followed up annually for between 4 - 7 years, depending on when they are recruited to the ASTIClite RCT. Secondary outcome measures for the follow up study are as follows:
1. Long-term efficacy (for those patients receiving HSCT), measured using documentation of the need for further treatment at each annual follow up visit

2. Documentation of disease activity at each annual follow up visit
3. Requirement for further medical or surgical intervention at each annual follow up visit
4. Disease-specific quality of life measured using the IBD-Q questionnaire at each annual follow up visit
5. Disease-specific quality of life measured using the IBD Control questionnaire at each annual follow up visit
6. Quality of life measured using the EQ-5D-5L questionnaire at each annual follow up visit
7. Health care resource utilisation measured using the healthcare resource use questionnaire at each annual follow up visit

Overall study start date
01/08/2017

Completion date
31/05/2021

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Participants must have consented to take part in the ASTIClite randomised controlled trial (see http://www.isrctn.com/ISRCTN17160440)
2. Participants must be willing and able to provide full informed consent, including sharing their data with the EBMT

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 99; UK Sample Size: 99

Key exclusion criteria
Significant language barriers, which are likely to affect the participant’s understanding of the study, or ability to complete outcome questionnaires

Date of first enrolment
01/04/2018

Date of final enrolment
21/06/2020

Locations

Countries of recruitment
United Kingdom

Study participating centre
University of Sheffield
United Kingdom
-

Sponsor information

Organisation
Barts Health NHS Trust

Sponsor details
c/o Mays Jawad
The Royal London Hospital
Whitechapel
London
England
United Kingdom
E1 1BB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 15/178/09

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 09/03/2021:
As the ASTIClite EBMT follow-up study was closed prior to any patients from the ASTIClite RCT trial rolled onto the follow-up study, there will be no results to publish for this study and participant-level data will not be available.

Previous publication and dissemination plan:
The protocol will be made available on the website of the trial funder (NIHR EME) at https://www.journalslibrary.nihr.ac.uk/programmes/eme/1517809/#/. Planned publication of the results in a high-impact peer reviewed journal in late 2026/early 2027.

Intention to publish date

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		31/05/2019	11/08/2022	Yes	No
HRA research summary			26/07/2023	No	No