Note-to-File

Date: 03/09/2018

Trial Title: SYCAMORE - randomised controlled trial of the clinical effectiveness, safety and cost effectiveness of Adalimumab in combination with methotrexate for the treatment of juvenile idiopathic arthritis

EudraCT No: 2010-021141-41
Sponsor: University Hospitals Bristol NHS Foundation Trust

Site Number: n/a **Patient Identifier (if applicable):** n/a

Subject: Data omitted from the final analysis report and EUDRA-CT results

During site close down for the trial, data was identified for participants that had not been sent to CTRC by sites and subsequently was not present in the database at the time of database lock.

The impact the data received has on the trial results was assessed by the statistics team who confirmed that the omitted data would have minimal impact on the trial results. Given the minimal impact on the results the database was not unlocked and this event was not considered a serious breach.

The omitted data is listed below:

Participant 0114011- Follow up diary

2 medications are listed, 1 is recorded on the concomitant medication CRF and the other calpol would not be used in the analysis as it does not meet permitted or non-permitted medications as per protocol. The other data captured related to service use and school attendance, the omission of this data would have minimal impact on the trial outcome.

Participant 0116001- Unscheduled visit

The visit occurred 3 weeks after the 3 month visit and therefore would not have been included in the assessment of treatment failure as per protocol there must be a minimum of 4 weeks in between assessments for treatment failure to be assessed. The CRF did not indicate any non permitted medication had been used.

Participant 0116002- 2 Adverse Events

2 AEs of sore throat were recorded, the data included would have minimal impact on the safety events reported.

Participant 0116004- Follow up diary

The medications listed were all recorded on the concomitant medication CRF. The other data captured related to service use and school attendance, the omission of this data would have minimal impact on the trial outcome.

Participant 0116061- 8 Adverse Events

8 AEs were reported however the start dates were not within the 30 day reporting window therefore this data would not have been included in the analysis if received prior to database lock.

Participant 0116067- Concomitant medication

2 entries of calpol were recorded and an entry of amoxicillin. These medications would not have been included in the analysis if they had been received prior to database lock as they do not meet the classification of medication permitted or medication not permitted recorded in the protocol.

Participant 0246030- 3 Adverse Events

3 AEs were reported however the start dates were not within the 30 day reporting window therefore this data would not have been included in the analysis if received prior to database lock.

Participant 0249031- 1 Adverse Event

1 AE was reported however this is a duplicate of a previously received AE, the data received contradicted the previously reported date of resolution and severity. This would have minimal impact on the safety outcomes.

Participant 0249083- Follow up visit 2, Follow up HUI and Follow up diary

The participant was already in the follow up phase of the trial therefore the data received did not impact the primary outcome of the trial.

Participant 0249083- 2 Steroid eye drops g. dexamethasone and g. cyclopentolate

The participant was already in the follow up phase of the trial therefore the data received did not impact the primary outcome of the trial as the participant could not meet treatment failure at this time point.

Signature:  Date: 03/09/2018

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Title: SENIOR DATA MANAGER