Welcome to the second paediatric rheumatology registers newsletter! Both the Biologics for Children with Rheumatic Diseases study (BCRD) and the BSPAR Etanercept Cohort Study (BSPAR ECS) are now coordinated by the Biologic Studies Group at the University of Manchester. The studies are run in parallel and this newsletter will provide regular updates on both of the studies.

BCRD: News and Updates

Happy 3rd Birthday to us!
We recruited our first patient in 4th May 2010, which means we have now been recruiting for 3 years. We are so thankful to everyone for their enthusiasm and support of the study, and look forward to being able to use the data in the coming years for analysis.

Recruitment Update

Ongoing recruitment – recruitment to Methotrexate cohort recommences!
We are pleased to announce that Arthritis Research UK have granted our budget supplement request and we now have the funds to recruit an additional 162 participants across both our cohorts.

As of 21/08/2013, BCRD is once again able to accept new methotrexate participants.

Recruiting methotrexate patients between BCRD and BSPAR ECS
BCRD and BSPAR ECS are now both in a position to recruit participants with JIA who are starting treatment with methotrexate for the first time. If you have R&D approval to recruit to both studies, could you please recruit to each study alternately where possible.

BSPAR ECS: News and Updates

Recruitment Update: Recruitment by centre since the time of study transition to University of Manchester (December 2012)

Table 1: Recruitment to the BSPAR Etanercept Cohort Study since the time of study transition to the University of Manchester (Dec 2012 onwards)

<table>
<thead>
<tr>
<th>Centre</th>
<th>Etanercept</th>
<th>Methotrexate</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birmingham Children’s Hospital</td>
<td>9</td>
<td>10</td>
<td>19</td>
</tr>
<tr>
<td>Alder Hey Hospital</td>
<td>9</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Royal Manchester Children’s Hospital</td>
<td>2</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Leeds General Infirmary</td>
<td>4</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Great Ormond Street</td>
<td>4</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Queen’s Medical Centre</td>
<td>3</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Sheffield Children’s Hospital</td>
<td>4</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Nuffield Orthopaedic Centre</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Norfolk and Norwich</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Leicester</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Poole</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Shrewsbury</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>University Hospital of North Staffs</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>41</td>
<td>26</td>
<td>69</td>
</tr>
</tbody>
</table>

Thank you to all centres who have recruited participants this year!

Total number of participants recruited in each cohort since the study began

<table>
<thead>
<tr>
<th>Etanercept Cohort</th>
<th>Methotrexate Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>771</td>
<td>230</td>
</tr>
</tbody>
</table>
Follow Up Update

We are thrilled with the return rate of our follow up questionnaires which remain at above 92% at each time point and hope that this is replicated in the return rates for the BSPAR study in the future.

**NEW** section for participants on website

A new section on the website has been developed for participants and their parents, to provide information and updates on the study. Please feel free to circulate the link amongst people you think may be interested in the study:

http://www.bcrdstudy.org/participants.asp

**NEW** section for participants on website

Collecting outstanding data - update

Once R&D approval has been given at your centre, you will receive a retrospective follow up questionnaire (v1: 16/04/2012) for each participant to collect data from the last time information was submitted to the study. These should be completed using information from the participant’s case notes.

Once completed, the forms should be returned to the study offices in Manchester in the postage-paid envelopes provided for entry on to the database by the study team.

Collecting follow-up data - going forward

Subsequent follow up forms should be entered directly on to the online data entry system. You will be prompted by the study coordinator to log in and complete these when they are due.

Conference news

Two abstracts have been accepted for presentation at the ACR conference, which will be held in San Diego in October:

Growth in Children and Adolescents With Juvenile Idiopathic Arthritis (JIA) After 2 Years Of Treatment With Etanercept: Results From The British Society For Paediatric and Adolescent Rheumatology (BSPAR) Etanercept Cohort Study. Rebecca Davies, accepted for oral presentation

Session Name: Paediatric Rheumatology - Clinical and Therapeutic Aspects Poster I: Juvenile Idiopathic Arthritis
Date and Session Time: Sunday, October 27, 2013, 8:30 AM - 4:00 PM
Location: San Diego Convention Centre: Exhibit Hall B2-C-D
Presentation Number: 291

Medically significant infections are increased in patients with juvenile idiopathic arthritis treated with etanercept. Results from the British Society for Paediatric and Adolescent Rheumatology (BSPAR) Etanercept Cohort Study. Rebecca Davies, accepted for oral presentation

Session Name: Paediatric Rheumatology - Clinical and Therapeutic Aspects III: Systemic Lupus Erythematosus and Other Disease Outcomes
Date and Session Time: Tuesday, October 29, 2013: 2:30 PM-4:00 PM
Presentation Time: 3:30-3:45PM
Location: Sapphire A (Hilton San Diego Bayfront Centre)
Presentation Number: 2678

The above abstracts have also been submitted to the BSPAR conference in Dublin in October

Lianne Kearsley-Fleet
Paediatric Registers Research Assistant

Lianne has worked on the paediatric biologics registers since 2012 and has a background in veterinary epidemiology, having gained a masters degree in this subject in 2011.

She aims to get more practical experience in data analyses and hopes to work towards a PhD.

Becky has a masters degree in sports and exercise psychology, and worked as a research assistant in the School of Psychological Sciences before moving to the Biologic Studies Group in 2009.

She is currently working towards a PhD by publication.
BCRD: BCRD requires a single blood sample from each participant at a time when blood is being taken for routine clinical purposes. This will be used for DNA extraction.

- Please contact Katy if you need a sample collection pack sending to you. This contains everything you need to obtain the sample, and includes postage paid packaging for its return to us.

Please remember to use study ID only on the collection tubes.
If you do not have a study ID, please do not collect blood.

Sample collection kit (L-R):
- pre-paid postage cardboard case
- security label
- 4ml sample collection tube
- sample paperwork
- plastic bag
- wadding

BCPAR ECS
- BCPAR ECS also requires a single blood sample from each participant at a time when blood is being taken for routine clinical purposes. This will be used for DNA extraction.
- For participants recruited before the transition to Manchester (pre December 2011) you will need to obtain additional consent: BCPAR ECS Retrospective Blood sample Collection Consent v2: 14/08/2012
- For participants recruited after the transition, the new consent form contains details regarding sample collection, so additional consent is not required.
- Contact Emily with any questions!

<table>
<thead>
<tr>
<th>Recruitment target</th>
<th>Biologic Cohort</th>
<th>Methotrexate Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants with JIA who have newly started a biologic therapy other than etanercept</td>
<td>Participants with JIA who have newly started methotrexate</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participant eligibility</th>
<th>Biologic Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Diagnosis of JIA</td>
<td></td>
</tr>
<tr>
<td>• Informed consent within six months of the first ever dose of the registration drug</td>
<td></td>
</tr>
<tr>
<td>• Can have received previous biologic therapies (including previous exposure to etanercept)</td>
<td></td>
</tr>
<tr>
<td>• Diagnosis of JIA</td>
<td></td>
</tr>
<tr>
<td>• Informed consent within six months of the first ever dose of methotrexate</td>
<td></td>
</tr>
<tr>
<td>• Must be biologic naive</td>
<td></td>
</tr>
</tbody>
</table>

Contact Details

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