ABI-JIA-P01 Study Newsletter

Anti-biopharmaceutical Immunization - Juvenile Idiopathic Arthritis Cohort

Pediatric Rheumatology INternational Trials Organisation

Issue 3 - September 2015

Dear Investigators, study managers and study coordinators,

We are pleased to release the 3rd issue of the study Newsletter for Abirisk JIA Cohort.

Congratulations! 58 patients have been already included in 5 countries.

This edition mainly focuses on the **decisions taken during the last Abirisk committee in Vienna** (5th and 6th September 2015). It also provides an update on patient recruitment.

The relevant news, described below, are the following:

1) the inclusion period has been extended to **31st March 2016**
2) the sample size has been recalculated
3) inclusion of **Etanercept** patients has been **stopped**.

Should you have any remarks or questions, do not hesitate to discuss the content with your monitoring team / Cohort leader.

- *Enrollment status (as of 15 September 2015).*
- *Number of patients expected: 120*
- *End of Inclusion period: 31 March 2016*
- *Centers: 48 across 16 countries; among the 26 centers who obtained Ethics Committee approval, 7 have included patients.*
- *EC approval pending for 22 centers.*

Up to now 58 patients are included.

Country	Patients Included
Greece	16
France	12
Italy	13
Czech Rep	16
Switzerland	1
TOTAL	58

Yours sincerely,

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The research leading to these results has received support from the Innovative Medicines Initiative Joint Undertaking under grant agreement n° [115303], resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution.

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Importants news

ABIRISK COMMITTEE MAIN DECISIONS – Vienna, 5th and 6th September 2015:

1- Extension of the inclusion period

Decision was taken by the Steering Committee in Vienna to extend the period of inclusion until the end of **MARCH 2016** (the initial period of inclusion of 18 months has now been extended to 24 months).

2- Extension of the study period

A 9 months extension of the project has been accepted by IMI. Consequently, the end of the project is now planned in November 2017.

3- Selection of patients

Given the remaining time for inclusion, 6 months, the total number of expected patients with JIA has been **decreased from 200 to 120.**

BUT, IMPORTANT: Inclusion of Etanercept patients is stopped.

The estimated number of patients to be included in each biotherapy has been modified:
- 30 patients to be included with Etanercept: inclusion stopped, objective reached with 31 patients.
- **30 patients to be included with Tocilizumab.** 13% objective reached with 4 patients included
- **60 patients to be included with Adalimumab.** 32% objective reached with 19 patients included

This new distribution is based on the fact that Etanercept patients are currently over-represented in the RA and JIA cohorts, and also on the limited immunologic potential of this drug, as documented in the literature to date.

Thus, it has been decided to stop the inclusion of Etanercept patients, and to favour the inclusion of patients on other drugs.

These modifications will be included in a new version of the protocol.

Thanks again to your site staff, your involvement in this program and all your patients. We really need all of them to drive such a large program to its conclusion

Thank you for taking the time to read this Newsletter!
The Study Team

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