

The Study

NEWSLETTER

Issue No. 1 (Nov 16)

TOP NEWS

The first patient was recruited to the EDIBLE trial on 10th August 2016 by Birmingham Children's Hospital in the UK.

Massive congratulations to the BCH team!!!

WHAT'S NEXT?

1. Ospedale Pediatrico Bambino Gesù and Medizinische Universität Wien are currently the leaders in the race for the next EDIBLE site to be opened.
2. Obtain approvals in all countries/ regions to move to protocol version 5.0 06/09/2016.
3. Open all sites by February 2017.

GETTING YOUR SITE OPEN

1. Provide signed & dated (within 2 years) CVs/GCP certificates for your team members.
2. Provide your centre's logo & address.
3. Provide the PI, dietitian & research nurse's telephone numbers.
4. Book your site training visit (2-4 hours required).
5. Engage with your legal department and try to urge them to review contracts fast (main cause of delay).
6. Return completed trial documents (i.e. training logs, acknowledgment receipts, delegation log) to CTRC promptly.
7. Perform randomisation system and database tests.

We are behind our targets for opening sites and need your help to get back on track! Please get in touch with any problems.

We can work together to achieve our goal!!!

REMINDERS

1. Return screening logs at the end of every month.
2. Send copies of consent forms/checklists to CTRC by fax/post within 7 days of patient recruitment.
3. Perform data entry within 7 days of patient visit.

BOOST AWARENESS

1. Please promote the trial by sharing and visiting our trial website <http://www.edible.org.uk/>
2. Help us become better by completing the PI mini survey.

WHO'S TAKING PART?

14 centres across EU take part in EDIBLE.

Open to patient recruitment:

4 UK: GOSH-London, Birmingham Children's Hospital, Bristol Royal Hospital for Children, Royal Manchester Children's Hospital
1 Italy: Ospedale Pediatrico Meyer-Florence

Trained and close to opening:

1 Italy: Ospedale Pediatrico Bambino Gesù-Rome
1 Austria: Medizinische Universität Wien
2 Germany: Krankenhaus Mara Bethel-Bielefeld, Schön Klinik Vogtareuth

Training and approval pending:

1 Czech Republic: Fakultní nemocnice v Motole-Prague
2 France: HFME Hospices Civils de Lyon, Hôpital de Hautepierre-Strasbourg
1 Switzerland: Hôpitaux Universitaires de Genève
1 UK: Royal Hospital for Sick Children-Edinburgh

USEFUL TIPS

Screening: Screen all patients with FCD Type II who are surgical candidates. When eligibility criteria changes please rescreen failed patients.

Consent: Obtain both consent and assent. Explain how both the diet and surgery are used to treat seizures. All patients will have surgery. We do not know which group will do best. Maintain equipoise.

Withdrawal: If a patient prematurely discontinues treatment (stops ketogenic diet or postpones surgery) it does not mean they must withdraw from the study.

FOR MORE DETAILS

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