ISRCTN57824306 https://doi.org/10.1186/ISRCTN57824306

Trial to Reduce Insulin-dependent diabetes mellitus in the Genetically at Risk

Submission date	Recruitment status
26/09/2005	No longer recruiting
Registration date	**Overall study status**
26/09/2005	Completed
Last Edited	**Condition category**
12/04/2019	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.TRIGR.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00179777

Secondary identifying numbers
MCT-49395

Study information

Scientific Title
Trial to Reduce Insulin dependent diabetes mellitus in the Genetically at Risk: a randomised controlled trial

Acronym
TRIGR

Study objectives
The hypothesis for this proposal holds that weaning to an extensively hydrolysed infant formula will decrease the incidence of type I diabetes, as it does in all relevant animal models for the disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Hospital District of Helsinki and UUSIMAA, Finland, 19/09/2000
2. The Ethical Committee of Paediatrics and Psychiatry, London Health Sciences Centre, London, Ontario, 02/05/2002

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Patient information can be found at: http://www.TRIGRNorthAmerica.org

Health condition(s) or problem(s) studied
Type 1 Diabetes Mellitus

Interventions
Experimental Arm:
Use of infant feed formula, cow milk based, extensively hydrolysed administered when needed

in supplementation or substitution for breast milk through 6 - 8 months from birth. (Formulated by MeadJohnson)

Control Arm:
Use of infant feed formula, cow milk based, non-hydrolysed administered when needed in supplementation or substitution for breast milk through 6 - 8 months from birth. (Formulated by MeadJohnson)

Trial details received: 12 Sept 2005

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Infant feed formulas

Primary outcome measure
Development of diabetes mellitus

Secondary outcome measures
1. Development of diabetes associated islet antibodies ICA, IAA, GADA Abs, IA-2A Abs
2. Development of cow milk protein antibodies

Overall study start date
01/03/2002

Completion date
31/05/2016

Eligibility

Key inclusion criteria
1. The biological parents and/or full (not half) sibling of the newborn infant has type 1 diabetes as defined by the World Health Organization
2. The infants parents or legal guardians give signed consent to participate

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
2730

Key exclusion criteria
1. An older sibling of the newborn infant has been included in the TRIGR intervention
2. Multiple gestation
3. The parents are unwilling or unable to feed the infant cows milk based products for any reason (e.g. religious, cultural)
4. The newborn infant has a recognisable severe illness such as those due to chromosomal abnormality, congenital malformation, respiratory failure needing assisted ventilation, enzyme deficiencies etc.
5. The gestational age of the newborn infant is less than 35 weeks
6. The infant is older than 7 days at randomisation
7. Inability of the family to take part in the study (e.g. the family has no access to any of the Study Centres, the family has no telephone)
8. The infant has received any infant formula other than Nutramigen prior to randomisation
9. No HLA sample drawn before the age of 8 days

Date of first enrolment
01/03/2002

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
Australia

Canada

Czech Republic

Estonia

Finland

Germany

Hungary

Italy

Luxembourg

Netherlands

Poland

Spain

Sweden

Switzerland

United States of America

Study participating centre
John P. Robarts Research Institute
London
Canada
N6A 5K8

Sponsor information

Organisation
John P. Robarts Research Institute (Canada)

Sponsor details
University of Helsinki, University of Pittsburgh, University of South Florida U.S. NIH funds for John Robarts Research Institute
P.O. Box 5015
100 Perth Drive
London
Canada
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Sponsor type
Not defined

ROR
https://ror.org/02grkyz14

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada), ref: MCT-49395

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
US Congress (USA)

Funder Name
National Institute of Child health and Human Development (NICHD) (USA)

Alternative Name(s)
NICHD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
Juvenile Diabetes Research Foundation (JDRF) (Direct) (UK)

Funder Name
European Foundation for the Study of Diabetes (EFSD)/JDRF/Novo Nordisk

Funder Name
Finnish Diabetes Research Foundation (Finland)

Funder Name
Academy of Finland (Finland)

Alternative Name(s)

Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Finland

Funder Name
Dutch Diabetes Research Foundation (Netherlands)

Alternative Name(s)
Dutch Diabetes Research Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Funder Name
European Union (EU)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	protocol	01/06/2007		Yes	No
Other publications	recruitment and retention strategies	01/04/2014		Yes	No
Results article	results	02/01/2018	12/04/2019	Yes	No