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
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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 |