

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

<b>Submission date</b> 26/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/09/2005	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 12/04/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00179777

**Protocol serial number**  
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

**Study type(s)**

Prevention

**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(s)**

Development of diabetes mellitus

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

All

**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)

**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, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, 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)**

Academy of Finland, Suomen Akatemia, Finlands Akademi, AKA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Research institutes and centers

**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

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	02/01/2018	12/04/2019	Yes	No
<a href="#">Protocol article</a>	protocol	01/06/2007		Yes	No
<a href="#">Other publications</a>	recruitment and retention strategies	01/04/2014		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes