

Online Only Supplemental Material

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This supplementary material has been provided by the authors to give readers additional information about their work

eTable 1. List of TRIGR Study Group Members

TRIGR STUDY GROUP

	<u>Last name</u>	<u>First name</u>	<u>Position</u>
Administration			
Data Safety Monitoring Board	Mandrup-Poulsen	Thomas	Chair
	Arjas	Elja	Member
	Lernmark	Åke	Member
	Läärä	Esa	Member
	Schmidt	Barbara	Member
	Krischer	Jeffrey P.	Observer
International Coordinating Center (ICC), Helsinki, Finland	Åkerblom	Hans K.	PI of the Study until 30.6.08, Deputy PI from 1.7.2008
	Hyytinen	Mila	European Study Monitor
	Knip	Mikael	Deputy PI until 30.6.2008, PI of the Study from 1.7.2008
	Koski	Katriina	National Investigator
	Koski	Matti	European Study Monitor
	Merentie	Kristiina	IT Specialist
	Pajakkala	Eeva	European Study Monitor
	Reunanen	Antti	European Study Monitor
	Salonen	Marja	Co-Investigator
	Terhonen	Tuija	Study Coordinator
	Virkkunen	Seija	Secretary
	Data Management Unit (DMU), Tampa, FL, USA	Cuthbertson	David
Gainer		Bruce	Biostatistician
Hadley		David	Programmer
Krischer		Jeffrey P.	Epidemiologist
Malloy		Jamie	PI of the DMU
Nallamshetty		Lavanya	Programmer
Shanker		Linda	Programmer
		Coordinator	

...continued **eTable 1.** List of TRIGR Study Group Members

Canadian Coordinating Center, London and Ottawa, ON	Bradley Dupré	Brenda John	National Coordinator Co-PI for North America, National Investigator
	Lough Nielsen Fraser	Gigi Debra William	National Coordinator Administrator Co-Investigator for Canada, Executive Committee
	Lawson	Margaret L.	Co-Investigator for Canada, Executive Committee
	Mahon	Jeffrey L.	Co-Investigator for Canada, Executive Committee
	Sermer	Mathew	Co-Investigator for Canada, Executive Committee
	Taback	Shayne P.	Co-Investigator for Canada, Executive Committee
	USA Coordinating Center, Pittsburgh, PA and Seattle, WA	Becker	Dorothy
Franciscus Nucci Palmer		Margaret Anita Jerry	National Coordinator Nutrition Coordinator of North America Executive Committee
Nutritional Epidemiology Unit, National Institute for Health and Welfare Helsinki, Finland		Alahuhta	Kirsi
	Bärlund	Sonja	Research Fellow
	Korhonen	Tuuli	Research Fellow
	Lehtonen	Eveliina	Research Fellow
	Pekkala	Minna	Research Fellow
	Sorkio	Susa	Research Fellow
	Vähätalo	Liisa	Research Fellow
	Virtanen	Suvi M.	Head of Nutritional Epidemiology Unit
	Uusitalo	Ulla	Research Fellow
	Öhman	Taina	Research fellow

...continued **eTable 1.** List of TRIGR Study Group Members

Countries	Study Centers			
Australia	AUS01 - Westmead - Children's Hospital	Bongiorno	Ros	Study Dietitian
		Catteau	Jacki	National Coordinator
		Fraser	Glenda	National Coordinator
		Howard	Neville	National Investigator
		Lloyd	Margaret	Study nurse
	AUS02 - Newcastle - John Hunter Children's Hospital	Crock	Patricia	Local Investigator
		Giles	Michelle	Study Nurse
		Siech	Krystyna	Study Nurse
		Wong See	Denise	Study Dietitian
AUS03 - Sydney - Sydney Children's Hospital	Brown	Christina	Study Dietitian	
	Catteau	Jacki	National Coordinator	
	Craig	Maria	Local Investigator	
	Johnston	Amanda	Study Dietitian	
Canada	CAN01 - London - St. Joseph's Health Care Centre	Bere	Lynda J.	Local Coordinator
		Clarson	Cheril L.	Local Investigator
		Jenner	Morris	Co-Investigator
		Mahon	Jeffrey L.	Co-Investigator
		McManus	Ruth	Co-Investigator
		Renato	Natale	Co-Investigator
	CAN02 - Vancouver - Children's and Women's Health Centre of British Columbia	Higo	Debbie	Local Coordinator
		Kent	Nancy	Co-Investigator
		Kozak	Sharon	
		Kwan	Jennifer	Coordinator (in Transition)
		Marshall	Colleen	Coordinator (In Transition)
		Metzger	Daniel	Local Investigator
		Stewart	Laura	Co-Investigator
		Taylor	Cheryl	
		Thompson	David	Local Investigator
Tong	Suet On			

...continued **eTable 1.** List of TRIGR Study Group Members

CAN03 - Calgary - Alberta Children's Hospital	Edwards	Alun	Co-Investigator
	Lange	Ian	Co-Investigator
	Mercer	Julia	
	Pacaud	Daniele	Co-Investigator
	Schwarz	Wendy	Local Coordinator
	Stephure	David K.	Local Investigator
	Swaby	Cheryl	
CAN04 - Edmonton - Walter MacKenzie Health Sciences	Baergen-Fladager	Sharlene	
	Boer	Jeanne	
	Chatur	Tameeza	Local Coordinator
	Chick	Connie	Co-Investigator
	Couch	Bob	Co-Investigator
	Demianczuk	Nestor	Local Investigator
	Girgis	Rose	Local Investigator
	Marks	Seth	Co-Investigator
	Ryan	Edmond	Co-Investigator
	Thompson	Marilyn	Local Coordinator
CAN05 - Winnipeg - Health Sciences Centre	Berard	Lori	
	Bloomfield	Erika	
	Catte	Daniel	Local Coordinator
	Dean	Heather J.	Co-Investigator
	Grant	Lorna	Co-Investigator
	Hamelin	Kathy	Co-Investigator
	LaForte	Janine	Local Coordinator
	Murphy	Liam	Co-Investigator
	Schneider	Carol	Co-Investigator
	Sellers	Elizabeth A.C.	Co-Investigator
	Taback	Shayne P.	Local Investigator
	Woo	Vincent	Co-Investigator
CAN06 - Ottawa - Children's Hospital of Eastern Ontario and The Ottawa Hospital	Boland	Alice	
	Bradley	Brenda	National Coordinator
	Clark	Heather D.	Co-Investigator
	Cooper	Tammy	
	Cormier	Roxanne	

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...continued **eTable 1.** List of TRIGR Study Group Members

	Frederick Good Gruslin Kane Karovitch Keely Lawson Lough Malcolm O'Shea Ranieri Rouatt Sauro Tawagi	Catherine Melanie Andrée Dominique Alan Erin Margaret L. Gigi Janine C. Elaine Mary Sharon Victor George F.	Co-Investigator Co-Investigator Local Investigator National Coordinator Co-Investigator Co-Investigator Co-Investigator Co-Investigator
CAN07 - Toronto Mount Sinai Hospital/Hospital for Sick Children	Andrighetti Aquilina Arnold Barrett Bartley Blumer Brush Daneman Donat Ehrlich Feig Gherson Gottesman Gysler Karkanis Kenshole Knight Lackie Lewis Martin Maxwell McLeod	Santina Andrea George Jon Connie Ian Cheryl Denis Diane Robert Denice Beth Irving Mathias Samuel Anne Byrton Elyse Valerie Mary Jean Cynthia Lynn	Co-Investigator Co-Investigator Co-Investigator Co-Investigator Local Investigator Co-Investigator Co-Investigator Co-Investigator Co-Investigator Co-Investigator Local Coordinator Co-Investigator

...continued **eTable 1.** List of TRIGR Study Group Members

	Oliver	Gillian	Co-Investigator
	Panchum	Paul	Co-Investigator
	Sermer	Mathew	Local Investigator
	Shillette	Nicholas	Co-Investigator
	Simone	Angelo	Co-Investigator
	Skidmore	Martin	Co-Investigator
	Turrini	Tania	
	Wong	Suzanne	Co-Investigator
CAN08 - Quebec - CHUQ	Allen	Christine	Co-Investigator
	Bélangier	Lise	Co-Investigator
	Bouchard	Isabelle	Co-Investigator
	Chapdelaine	Magalie	
	Ferland	Suzanne	Local Coordinator
	Frenette	Line	Local Investigator
	Garrido-Russo	Maria	Co-Investigator
	Latulippe	Diane	
	Leblanc	Mylene	Local Coordinator
	Imbeault	Jérôme	
	Marc	Isabelle	
	Morin	Valérie	Local Investigator
	Olivier	Guy	Co-Investigator
	Weisnagell	John	Co-Investigator
CAN09 - Saint John Regional Hospital - Horizon Health Network	Costain	Garry	Co-Investigator
	Dornan	John	Co-Investigator
	Heath	Kathy	Local Coordinator
	MacSween	Mary-Catherine	Co-Investigator
	McGibbon	Angela	
	Ramsay	Carolyn	
	Sanderson	Frank	Co-Investigator
	Sanderson	Susan	Local Investigator
CAN10 - Montreal - L' Hôpital Sainte-Justine	Anctil	Colette	
	Benabdesselam	Linda	
	Fraser	William	Co-Investigator
	Gonthier	Monique	Co-Investigator

...continued **eTable 1.** List of TRIGR Study Group Members

	Huot	Céline	Local Investigator
	Lagace	Maryse	Back-up Nurse
	Lortie	Louise	
	Roy	Chantal	
	Thibeault	Maryse	Local Coordinator
CAN11 - Montreal Children's Hospital	Diotalevi	Sabrina	
	Gagné	Valérie	
	Laforte	Diane	Local Coordinator
	Legault	Laurent	Local Investigator
	Perron	Patrice	Co-Investigator
CAN12 - Halifax - IWK Health Centre/Dalhousie	Armson	Anthony	Co-Investigator
	Canning	Paula	
	Cummings	Elizabeth A.	Local Investigator
	Hardie	Rebecca	Local Coordinator
	Ivanko	Vanda	
	McLeod	Lynne	Co-Investigator
	McPhee	Anita	
	Mokashi	Arati	Co-Investigator
	Morrison	Lisa	
	Scott	Karen	Local Coordinator
CAN13 - St. John's - Janeway Child Health Center	Bridger	Tracey	Local Investigator
	Crane	Joan	Co-Investigator
	Crummell	Cheryl	Local Coordinator
	Curtis	Joseph C.	Co-Investigator
	Dawson	Colette	
	Grant	Marie	
	Joyce	Carol	Co-Investigator
	Newhook	Leigh Anne	Co-Investigator
CAN14 - Kingston - Kingston General Hospital/ Queen's University	Begum-Hasan	Jahanara	Co-Investigator
	Breen	Adriana	Local Coordinator
	Chambers	Beverly	
	Houlden	Robyn	Local Investigator

...continued **eTable 1.** List of TRIGR Study Group Members

		Woods	Marie	
	CAN15 - Regina - Regina Qu'Appelle	Carrson Kelly	George Sheila	Local Investigator Local Coordinator
	CAN16 - Saskatoon - Royal University Hospital	Andreychuk Martel Penner Sankaran	Brenda Marie, Jocelyne Marie Koravangattu	Co-Investigator Local Coordinator Local Investigator
	CAN17 - Peterborough - Peterborough Regional Health Centre	Burnie Hardy-Brown King White	Shay Karolyn Nancy Richard A.	Local Coordinator Local Coordinator Local Investigator
	CAN18 - Victoria - Vancouver Island Health Research Centre	Park Peters Popkin Robson	Marilyn Delane James Laurie	Local Investigator Local Coordinator
Czech Republic	CZE01 - Prague - Faculty Hospital Kralovske Vinohrady	Al Taji Aldhoon Cerna Cerny Francova Hainerova Kothankova Koukalova Krakorova Mendlova Romanova Sitova Stechova Vavrinec Vosahlo Zlatohlavkova	Eva Irena Marcela Milos Helena Irena Hana Renata Vladimira Pavla Martina Radka Katerina Jan Jan Blanka	National Coordinator Co-Investigator Co-Investigator Co-Investigator Study Nurse Co-Investigator Study Nurse Study Nurse Study Nurse National Coordinator Co-Investigator Study Dietitian Co-Investigator National Investigator Co-Investigator Co-Investigator

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	CZE02 - Brno - Hospital Milosrdnych Bratri	Brazdova	Ludmila	Local Investigator
	CZE03- Olomouc - Faculty Hospital Olomouc	Faksova Gregorova Kantor Malkova Venhacova Venhacova	Petra Dana Lumir Kamila Jitrenka Petra	Study Nurse Study Nurse Co-Investigator Study Nurse Local Investigator Co-Investigator
	CZE04 - Usti nad Labem - Hospital of Masaryk	Cipra Skvor	Adam Jaroslav	Local Investigator Co-Investigator
	CZE05 - Ceske Budejovice - Hospital Ceske Budejovice	Tomsikova	Zdenka	Local Investigator
	CZE06 - Plzen - Faculty Hospital Plzen	Botkova-Krauseova Mockova Krcikova	Hana Alice Petra	Local Investigator Co-Investigator Local Investigator
	CZE07 - Zlin - Hospital of Bata	Gogelova Kandrnalova	Pavla Jitka	Local Investigator Local Investigator
Estonia	EST01 - Tallinn - Tallinn Children's Hospital	Einberg Jakovlev Krassotkina Rannaste Raukas Riikjäv Mark	Ülle Ülle Svetlana Eve Reet Mall-Anne Kairit	Co-Investigator Co-Investigator Study Nurse Study Nurse Co-Investigator Local Investigator Study Nurse
	EST02 - Tartu - Tartu University Children's Hospital	Astover Kirss Ormisson Retpap Täht	Valve Anne Anne Jana Ene	Co-Investigator Co-Investigator National Investigator Study Nurse Study Nurse

...continued eTable 1. List of TRIGR Study Group Members

		Tillmann Vahtra	Vallo Sille	Co-Investigator Study assistant
Finland	FIN01 - Helsinki - Children's Hospital, University of Helsinki	Åkerblom	Hans K.	Co-Investigator
		Heikkilä	Maija	National Nutrition Coordinator
		Luopajarvi	Kristiina	Local Investigator
		Kleemola	Päivi	
		Knip	Mikael	National Investigator
		Laukkanen	Elina	Local Coordinator
		Parkkola	Anna	Local Investigator
		Pigg	Hanna-Mari	National Nutrition Coordinator
		Puttonen	Hilkka	National Coordinator
		Renlund	Martin	Co-Investigator
		Suomalainen	Heli	National Coordinator
		Tenkula	Tarja	Local Coordinator
		Teramo	Kari	Co-Investigator
	FIN02 - Helsinki - Department of Obstetrics and Gynecology, University of Helsinki	Järvenpää	Anna-Liisa	Local Investigator
	FIN03 - Espoo - Jorvi Hospital	Hämäläinen Jussila	Anu-Maaria Rea	Local Investigator Study Nurse
	FIN04 - Kotka - Kymenlaakso Central Hospital	Haavisto	Hannu	Local Investigator
		Holopainen	Seija	Study Nurse
		Kupiainen	Harriet	Study Dietitian
		Leeve	Tuula	Study Nurse
		Lumme	Kari	Co-Investigator
		Nironen	Tuula	Study Dietitian
		Tenhola	Sirpa	Local Investigator
		Tiilikainen	Teea	Study Nurse

...continued **eTable 1.** List of TRIGR Study Group Members

FIN05 - Lahti - Paijat-Hame Central Hospital	Keinonen	Hilkka	Study Dietitian
	Lautala	Pentti	Local Investigator
	Salonen	Pia	Local Investigator
	Vesanto	Maarit	Study Nurse
FIN06 - Tampere - Department of Pediatrics, Tampere University Hospital	Aspholm	Anna Susanna Helena	Local Investigator
	Asunta	Paula	Local Coordinator
	Ikävalko	Heidi	Study Nurse
	Jäminki	Sinikka	Local Coordinator
	Kekki	Päivi	Co-Investigator
	Koskinen	Merja	Study Nurse
	Lehtimäki	Susanna	Study Nurse
	Lähde	Jyrki	Local Investigator
	Mäkelä	Mariariitta	Study Dietitian
	Peltoniemi	Sari	Co-Investigator
	Poutiainen	Laura	Study Dietitian
	Ranta	Kari	Co-Investigator
	Salonsaari	Tiina	Co-Investigator
	Sarviharju-Tujula	Sanna-Leena	Co-Investigator
Siljander	Heli	Co-Investigator	
FIN07 - Pori - Satakunta Central Hospital	Haanpaa	Pirkko-Liisa	Study Nurse
	Holm	Carita	Local Investigator
	Järveläinen	Virpi	Study Dietitian
	Kangaskolkka- Keskilohko	Anna-Mari	Study Nurse
	Laino	Eila	Study Nurse
	Marjamäki	Liisa	Study Dietitian
	Suominen	Eila	Study Dietitian
	Ylitalo	Samuli	Local Investigator
FIN08 - Jyväskylä - Central Finland Central Hospital	Hokkanen	Marika	Study Nurse
	Lounamaa	Raisa	Co-Investigator
	Matikainen	Minna	Study Dietitian
	Nuuja	Anja	Local Investigator
	Puupponen	Anna Riikka	Study Nurse

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	Salo-Edwards	Heli	Study Nurse
FIN09 - Seinäjoki - South Ostrobothnia Central Hospital	Alanne	Soili	Study Dietitian
	Kultti	Tiina	Study Nurse
	Linjama	Hilpi	Study Dietitian
	Muhonen	Katja	Study Dietitian
	Sauna-aho	Maija	Study Dietitian
	Talvitie	Timo	Local Investigator
FIN10 - Hyvinkää - Hyvinkää Hospital	Backman	Mirja	Study Nurse
	Hanhijärvi	Raija	Local Investigator
	Koivula	Pirjo	Study Nurse
	Lindström	Kaija	Local Investigator
	Martikainen	Anni	Study Dietitian
	Nurmi	Pirjo	Study Dietitian
FIN11 - Kuopio - Department of Pediatrics, Kuopio University Hospital	Björk	Anne	Local Coordinator
	Huopio	Hanna	Local Investigator
	Komulainen	Jorma	Local Investigator
	Lehtomäki	Soili	Study Dietitian
	Muikku	Eeva	Study Nurse
	Pesola	Jouni	Co-Investigator
	Sankilampi	Ulla	Co-Investigator
FIN12 - Oulu - Department of Pediatrics, Oulu University Hospital	Arkkola	Tuula	Study Dietitian
	Hekkala	Anne	Co-Investigator
	Jurvakainen	Sanna	Study Nurse
	Koivikko	Minna-Liisa	Study Nurse
	Kähönen	Miia	Study Nurse
	Leinonen	Erja	Co-Investigator
	Mykkänen	Teija	Study Nurse
	Pohjola	Hilkka	Local Coordinator
	Riikonen	Kaisu	Study Nurse
	Niittyvuopio	Aune	Local Coordinator
	Stenius	Aino	Study Nurse
	Tapanainen	Päivi	Co-Investigator
	Veijola	Riitta	Local Investigator

...continued **eTable 1.** List of TRIGR Study Group Members

FIN13 - Hämeenlinna - Kanta-Häme Central Hospital	Alar	Abram	Local Investigator	
	Jovio	Senja	Study Nurse	
	Korpela	Paavo	Local Investigator	
	Mäkinen	Enja	Study Dietitian	
FIN14 - Vaasa - Vaasa Central Hospital	Hietanen	Liisa	Study Nurse	
	Kivistö	Johanna	Study Nurse	
	Käär	Marja-Liisa	Local Investigator	
	Lehtimäki	Päivi	Study Nurse	
	Mustila	Taina	Local Investigator	
	Popov	Erik	Local Investigator	
	Säätelä	Sirkku	Study Nurse	
	Taittonen	Leena	Local Investigator	
FIN15 - Lappeenranta - South Carelian Central Hospital	Ahtiainen	Krista	Local Investigator	
	Laaksonen	Nina	Study Dietitian	
	Luoto	Minna	Study Nurse	
	Viitala	Juha	Local Investigator	
	Virransalo	Ritva	Local Investigator	
FIN16 - Mikkeli - Mikkeli Central Hospital	Nykänen	Päivi	Local Investigator	
	Paajanen	Satu	Study Nurse	
	Parkkinen	Satu	Study Dietitian	
	Pyrhönen	Heli	Study Dietitian	
	Särkkä	Terttu	Study Nurse	
Germany	GER01 - Hannover - Kinderkranken-haus auf der Bult	Aschemeier	Bärbel	National Coordinator
		Bektas	Sevim	Study Nurse
		Danne	Thomas	National Investigator
		Datz	Nicolin	Co-Investigator
		Deiss	Dorothee	Co-Investigator
		Kordonouri	Olga	Co-Investigator
		Lüpke	Kerstin	Co-Investigator
		Müller	Babette	Study Nurse
		Nestoris	Claudia	Co-Investigator
		Roths	Silke	Study Nurse

...continued **eTable 1.** List of TRIGR Study Group Members

		Sadeghian	Evelin	Dietitian		
		Semler	Kerstin	Study Nurse		
Hungary	HUN01 - Budapest - Semmelweis Medical University	Arató	András	Co-Investigator		
		Krikovszky	Dóra	Co-Investigator		
		Madácsy	László	National Investigator		
		Nobilis	András	Co-Investigator		
		Szénási	József	Study Nurse		
Italy	ITA01 - Rome - University Campus Bio-Medico of Rome	Benevento	Danila	Co-Investigator		
		Beretta Anguissola	Giuseppina	Co-Investigator		
		Biagioni	Martina	Co-Investigator		
		Bizzarri	Carla	Co-Investigator		
		Cherubini	Valentino	Co-Investigator		
		Giordano	Carla	Co-Investigator		
		Giorgetti	Chiara	Co-Investigator		
		Khazrai	Yeganeh Manon	Local Coordinator		
		Kyanvash	Shadi	Co-investigator		
		Maddaloni	Ernesto	Local Coordinator		
		Napoli	Angela	Co-Investigator		
		Piergiovanni	Fabio	Co-Investigator		
		Pitocco	Dario	Co-Investigator		
		Pozzilli	Paolo	National Investigator		
		Suraci	Titti	Co-Investigator		
		Valente	Luciana	Laboratory technician		
		Visalli	Natalia	Co-Investigator		
			SAR01 - Cagliari - St. Michele Hospital	Carboni	M. Battistina	Study Dietitian
				Casu	Anna	Co-Investigator
				Cavallo	Roberta	
	Cau	Valeria		Co-Investigator		
	Isola	Christina		Co-Investigator		
	Ledda	Alessia		Study Biologist		
	Loddo	Miriam		Study Biologist		
	Mannu	Carla		Local Coordinator		
	Pettinau	Marcella		Study Biologist		
	Pisano	Silvia		Co-Investigator		

...continued **eTable 1.** List of TRIGR Study Group Members

		Porceddu Putzu Rita Songini	Monica Claudia Angioni Marco	Secretary Co-Investigator Co-Investigator National Investigator
Luxembourg	LUX01 - Luxembourg - Centre Hospitalier de Luxembourg	de Beaufort Peters Schierloh	Carine Danielle Ulrike	National Investigator Study Dietitian Co-Investigator
The Netherlands	NET01 - Rotterdam - Sophia Children's Hospital	Bruining Bisschoff Blonk Lappenschaar Manai Seesink Sperling-Conrad Verhagen Zoethout	Jan Margriet Linda Tanja Badies Maaike Mona Marit Jan Age	National Investigator National Coordinator Study Dietitian Study Dietitian Study Nurse Study Dietitian Study Dietitian Study Nurse
Poland	POL01 - Wroclaw - Medical University of Wroclaw	Basiak Chalas Chesiak Gramza Iwankiewicz Sieradzan Wasikowa Wikiera	Aleksander Mariola Maria Agnieszka Joanna Elzbieta Renata Beata	CoInvestigator Study Nurse Laboratory Assistant Study Assistant Co-Investigator Study Nurse National Investigator Co-Investigator
	POL02 - Krakow - Polish-American Children's Hospital	Ciechanowska Dziatkowiak Futona Górska Głowacka-Woźny Kaim Klich Starzyk	Marta Hanna Bernadetta Aleksandra Malgorzata Irena Barbara Jerzy	Local Investigator Co-Investigator Study Nurse Co-Investigator Study Nurse Co-Investigator Laboratory Assistant Co-Investigator

...continued **eTable 1.** List of TRIGR Study Group Members

		Styrna Tokarska	Monika Lidia	Dietician Co-Investigator
	POL03 - Katowice - Medical University of Silesia	Chucherco Deja Firek-Pedras Jarosz-Chobot Kalina Kutrowska-Adamusiak Minkina-Pedras Muchacka-Bianga	Dorota Grazyna Malgorzata Przemyslawa Maria Krystyna Mariola Malgorzata	Study Nurse Co-Investigator Co-Investigator Local Investigator Co-Investigator Co-Investigator Co-Investigator Co-Investigator
	POL04 - Lodz - Medical University of Lodz	Bodalski Mlynarski Szadkowska	Jerzy Wojciech Agnieszka	Co-Investigator Co-Investigator Local Investigator
	POL05 - Lodz - Polish Mother's Memorial Hospital (I.C.Z.M.P)	Cieslak Cytryk Dziasosz Jastzebowska Krysiak Szymanska Wilczyński Zawodniak-Szalapska	Agnieszka Katarzyna Krzysztof Joanna Anna Ursula Jan Malgorzata	Study Nurse Local Investigator Co-Investigator Study Nurse Study Nurse Study Nurse Co-Investigator Co-Investigator
Spain	SPA01 Hospital Universitario Cruces, BioCruces, UPV/EHU, CIBERDEM, CIBERER Bilbao, Spain	Aguayo Bilbao Castano Chueca Cortazar Echarte Gonzalez Frutos Jimenez Martul Moreno Oyarzabal Rica	Anibal Jose Ramon Luis Maria Alicia Goretti Teba Paloma Pedro Ana Mirentxu Itxaso	Co-Investigator Co-Investigator National Investigator Co-Investigator Co-Investigator Study Nurse Local Coordinator Study Nurse Co-Investigator Study Nurse Co-Investigator Co-Investigator

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	Salgado	Yolanda	Study Nurse
Hospital Clínico San Carlos- Coordinator Center	Serrano-Ríos Martínez-Larrad	Manuel María Teresa	National Investigator Local Coordinator
SPA02 - Madrid - Hospital Clinico San Carlos	Hawkins Herranz Pallardo Saez de Ibarra	Federico Gustavo Lucrecia Luis Felipe Lourdes	Co-Investigator Co-Investigator Co-Investigator Study Nurse
SPA03 - Madrid - Hospital Gregorio Marañón	Huidobro Fernandez Leon Luis Ortíz-Quintana Pintado Recarte Rodriguez Arnau	Belén Juan Luis Pilar Dolores	Co-Investigator Co-Investigator Co-Investigator Co-Investigator Co-Investigator
Sweden			
SWE01 - Linköping - University of Linköping	Aronsson Bodén Fredriksson Isacsson Johansson Karlsson Lock Ludvigsson Sandström Smolinska Konefal	Linda Stina Jenny Eva Ingela Erika Charlotta Johnny Ann-Marie Malgorzata	Study Dietitian Study Dietitian Study Nurse Study Nurse National Coordinator Study Dietitian National Investigator Study Nurse National Coordinator
SWE02 - Uddevalla - Uddevalla Hospital	Andreasson Dahlström Hanas Lundqvist Windell	Catarina Ulla Ragnar Kristin Lena	Study Dietitian Study Dietitian Local Investigator Study Nurse Study Nurse
SWE03 - Göteborg - GothenburgThe Queen Silvia	Jansson Karlsson	Inger Ann-Katrine	Study Nurse Study Nurse

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Children's Hospital	Lindbladh	Bengt	Local Investigator
	Odenman	Ingrid	Study Dietitian
	Pettersson	Carina	Study Nurse
	Sundqvist	Maud	Study Nurse
SWE05 - Halmstad - Halmstad Hospital	Aronsson	Stefan	Study Doctor
	Bellman	Ingegerd	Study Dietitian
	Bengtsson	Ann-Britt	Study Nurse
	Lydén	Gun-Britt	Laboratory technician
	Nilsson	Nils-Östen	Local Investigator
	Söderblom Unt	Maj Cecilia	Study Dietitian Study Nurse
SWE06 - Trollhättan - Trollhättan Hospital	Bengtsson	Malin	Study Dietitian
	Fors	Hans	Local Investigator
	Helmrich	Anneli	Study Dietitian
	Osland Johansson	Turid	Study Dietitian
SWE07 - Norrköping - Vrinnevi Hospital	Andersson	Ann-Catrin	Study Nurse
	Hellgren	Gudrun	Study Nurse
	Källsholm	Helena	Dietician
	Lindqvist	Josefina	Study Nurse
	Nilsson	Mona	Study Dietitian
	Nordwall	Maria	Local Investigator
	Åhsberg	carolina	Study nurse
SWE08 - Borås - Borås Hospital	Lindh	Agne	Local Investigator
	Lindhe	Catarina	Study Dietitian
	Samuelsson	Carina	Study Dietitian
	Wiik	Annica	Study Nurse
SWE09 - Karskrona - Karlskrona Hospital	Edenwall	Hans	Local Investigator
	Persson	Ing-Britt	Study Dietitian
	Strigard	Eva	Study Nurse
	Svensson	Britt-Louise	Study Nurse

...continued **eTable 1.** List of TRIGR Study Group Members

	SWE10 - Örebro - University Hospital	Åman Breivik Detlofsson Kroon	Jan Gun-Eli Inga-Lill Marianne	Local Investigator Study Nurse Study Dietitian Study Nurse
	SWE11 - Jönköping - Ryhovs Hospital	Johansson Ilvered Lundberg Åkesson	Calle Rosita Anna Karin	Local Investigator Study Nurse Study Nurse Local Investigator
Switzerland	SWT01 - Zürich - University Children's Hospital	Beccarelli Gadient Rappold-Amrein Schoenle	Angela Margrit Christina Eugen	Study Dietitian Local Coordinator Study Dietitian National Investigator
USA	USA01 - Pittsburgh - Children's Hospital of Pittsburgh	Becker Daftary Damagro-Elias Franciscus Gilmour Klein Lain Salerno Smith Vats	Dorothy Ashi Mary Ellen Margaret Carol Mary Beth Christine Dawn Mary Ellen Kalyani	USA National Investigator / Pittsburgh Local Investigator Co-Investigator Study Dietitian USA Coordinator / Pittsburgh Coordinator Co-Investigator Study Nurse Co-Investigator Study Nurse Study Dietitian Co-Investigator
	USA02 - Seattle - Puget Sound Health System	Jones Pfaff Malone Mansfield Munns Nickel Palmer Pompilio	Dawn Patricia Pam Misty Katherine Jerry Kristin	Research Assistant Study Coordinator Study Coordinator Coordinator Coordinator Local-Investigator Coordinator

...continued **eTable 1.** List of TRIGR Study Group Members

	Siemion	Wendy	Study Nurse
	Taculad	Rachel	Coordinator
	Van Horn	Kelly	Study Dietitian
	Zdanadewic	Megan	Study Dietitian
USA03 - St. Louis - Washington University	Chambliss	Cheryl	Study Nurse
	Jones	Jackie	Recruiter
	Sadler	Michelle	Study Nurse
	Tanner-Blasiar	Marilyn	Coordinator
	White	Neil	Local-Investigator
USA04 - Los Angeles - Mattel Children's Hospital of UCLA	Bell	Cindy	Study Nurse
	Camper	Natalie	Study Nurse
	Devaskar	Sherin	Co-Investigator
	Devaskar	Uday	Local-Investigator
	Horowitz	Heather	Coordinator/dietitian
	Rogers	Lisa	Coordinator/dietitian
	Shannahan	Randi	Research Assistant
	Silk	Karin	Study Nurse
USA05 - Ponce - Ponce School of Medicine	Bermudez	Zildalee	Recruiter
	Colon	Roxana	Coordinator
	Frazer	Teresa	Co-Investigator
	Martinez-Nieves	Brenda	Study Dietitian
	Torres	Jose	Local Investigator
	Vega	Jose	Dietitian
USA06 - New York - Naomie Berrie Diabetes Center	Chan	Mary	Research Assistant
	Cook	Steve	Research Assistant
	Goland	Robin	Local Investigator
	Greenberg	Ellen	Coordinator
	Jules	Nadimire	Research Technician
	Montes	Jennifer	Research Assistant
	Nelson	Maudene	Dietitian
	Schachner	Holly	Co-Investigator
	Softness	Barney	Co-Investigator

...continued **eTable 1.** List of TRIGR Study Group Members

Laboratories				
HLA-typing Laboratory - Turku - Finland	Ilonen	Jorma	Head of HLA-typing Laboratory	
	Kiviniemi	Minna	Laboratory Manager	
HLA-typing Laboratory - Pittsburgh - PA - USA	Suominen	Ritva	Technician	
	Alexander	Angela	Technician	
	Hyrckowian	Elizabeth	Chief Technician	
	Nichol	Lynn		
Cow's Milk Antibody Laboratory - Helsinki - Finland	Stefura	Christopher	Head of HLA-typing Laboratory	
	Trucco	Massimo		
	Karjalainen	Erja	Secretary	
	Louhio	Terttu	Technician	
	Sarnesto	Annikki	Co-Investigator	
Autoantibody Laboratory - Helsinki - Finland	Savilahti	Erkki	Head of Cow's Milk Antibody Laboratory	
	Valtonen	Elsa	Co-Investigator	
	Davydova	Berta	Technician	
	Helander	Sinikka	Technician	
	Hämäläinen	Juho	Technician	
	Härkönen	Taina	Co-Investigator	
	Joutsjoki	Leni	Technician	
	Kararic	Mevlida	Technician	
	Knip	Mikael	Deputy PI until 30.6.08, PI of the Study from 1.7.08, Head of Antibody Laboratory	
	Latva-Koivisto	Markku	Technician	
	Lönn	Eija	Technician	
	Nurmi	Tiina	Technician	
	Ollila	Iris	Technician	
Rinkinen	Jukka	Technician		
Ronkainen	Matti	Co-Investigator		
Tukiainen	Helena	Technician		

...continued **eTable 1.** List of TRIGR Study Group Members

T-Cell Laboratory - Helsinki - Finland	Cederlöf	Annika	Technician
	Kiikeri	Maria	Technician
	Luopajarvi	Kristiina	Local investigator
	Tsupari	Sinikka	Technician
	Vaarala	Outi	Head of T-cell Laboratory
T-Cell Laboratory - Toronto - ON - Canada	Cheung	Roy	
	Bryant	Kirsten	Technician
	Chan	Yin	Graduate Student
	Dosch	Hans-Michael	Head of T-Cell Laboratory
	Maezawa	Yuko	Fellow
	Paltser	Geoffrey	Graduate Student
	Rasavi	Rozy	Graduate Student
	Tsui	Hubert	Fellow
	Winer	Shawn	Fellow
	Wu	Ping	Technician
	Yantha	Jason	Graduate Student

eTable 2. The Autoantibody Reactivity Appearing First in the Casein Hydrolysate Group and in the Control Group

Autoantibody reactivity	Casein hydrolysate group (N=139)	Control Group (n=117)	P value
Islet cell antibodies (ICA), n (%)	23 (16.6%)	18 (15.4%)	.80
Insulin autoantibodies (IAA), n (%)	27 (19.4%)	20 (17.1%)	.63
Antibodies to GAD (GADA),n (%)	27 (19.4%)	19 (16.2%)	.51
Antibodies to IA-2 (IA-2A), n (%)	0 (0.0%)	2 (1.7%)	.12
Two autoantibodies	35 (25.1%)	29 (24.8%)	.94
- ICA + IAA, n (%)	12 (8.6%)	7 (6.0%)	.42
- ICA+GADA, n (%)	12 (8.6%)	9 (7.7%)	.78
- ICA +IA-2A, n (%)	1 (0.4%)	2 (1.7%)	.46
- IAA + GADA, n (%)	8 (5.8%)	7 (6.0%)	.94
- IAA + IA-2A, n (%)	1 (0.7%)	1 (0.9%)	.90
- GADA + IA-2A, n (%)	1 (0.7%)	3 (2.6%)	.24
Three autoantibodies	20 (14.4%)	17 (14.5%)	.97
- ICA + IAA + GADA, n (%)	16 (11.5%)	14 (12.0%)	.91
- ICA + IAA + IA-2A, n (%)	1 (0.7%)	2 (1.7%)	.46
- ICA + GADA + IA-2A, n (%)	2 (1.4%)	0 (0.0%)	.19
- IAA + GADA + IA-2A, n (%)	1 (0.7%)	1 (0.9%)	.90
All four autoantibodies, n (%)	7 (5.0%)	12 (10.3%)	.11

eTable 3. Initial and Maximal Autoantibody Titers in the Casein Hydrolysate Group and in the Control Group

Autoantibody titers (median and interquartile range, [] = the number of positive children) in the first autoantibody-positive sample and in the sample with the maximal titer in the casein hydrolysate group and in the control group among those with multiple autoantibodies.

Autoantibody reactivity	Casein hydrolysate group (N=139)	Control group (n=117)	P value
Islet cell antibodies			
- first positive titer, JDFU*	16 (4 – 17.1) [139]	13 (4 – 93) [117]	0.531
- maximal titer, JDFU	128 (32 – 380) [139]	160 (23 – 512) [117]	0.229
Insulin autoantibodies			
- first positive titer, RU**	7.1 (4.0 – 17.1) [111]	6.8 (4.4 – 12.9) [94]	0.829
- maximal titer, RU	15.5 (6.4 – 33.1) [139]	13.3 (4.6 – 35.4) [117]	0.381
Antibodies to GAD			
- first positive titer, RU	30.0 (13.6 – 85.8) [122]	22.0 (12.0 – 65.3) [98]	0.176
- maximal titer, RU	71.5 (18.2 – 420.1) [139]	40.9 (13.9 – 308.1) [117]	0.060
Antibodies to IA-2			
- first positive titer, RU	37.8 (4.1 – 119.6) [90]	12.7 (2.7 – 80.9) [82]	0.068
- maximal titer, RU	26.6 (0.3 – 285.4) [139]	32.1 (0.5 – 302.3) [117]	0.900

*JDFU; Juvenile Diabetes Foundation units, **RU; relative units

eTable 4. Reported Adverse Events in the 2 Arms of the TRIGR Study

Event	Casein Hydrolysate			Control Formula			P-Value
	Number of Participants	Number of Events	Events/ Month of Follow-Up	Number of Participants	Number of Events	Events/ Month of Follow-Up	
Upper Respiratory Infection	747	4942	0.0508	765	5121	0.0517	0.3835
Gastroenteritis	471	1323	0.0136	482	1258	0.0127	0.0816
Urinary Tract Infection	79	125	0.0013	91	115	0.0012	0.4318
Middle Ear Infection	510	1674	0.0172	523	1829	0.0185	0.0375
Pneumonia	86	99	0.0010	85	112	0.0011	0.4458
Other Infection	723	2779	0.0286	737	2820	0.0285	0.8941
Suspected Study Formula Intolerance	52	64	0.0007	60	78	0.0008	0.2869
Asthma, Other Forms of Allergy	293	548	0.0056	309	620	0.0063	0.0727
Malignancy	2	2	0.0000	1	1	0.0000	0.5614
Accident (Not Requiring Hospitalization)	111	145	0.0015	116	144	0.0015	0.8309
Accident (Requiring Hospitalization)	16	17	0.0002	22	24	0.0002	0.3028
Death	5	5	0.0001	4	4	0.0000	0.4688
Other	855	3955	0.0406	833	3949	0.0398	0.3807
Hypoglycemia requiring IV glucose	10	10	0.0001	20	20	0.0003	0.0814
Event requiring inpatient hospitalization or prolongation of existing hospitalization	38	51	0.0007	37	43	0.0006	0.3617
Life-threatening event	2	2	0.0000	3	3	0.0000	0.6714
Persistent or significant disability/incapacity	1	2	0.0000	3	3	0.0000	0.6714
Any Infection	938	9520	0.0978	933	9885	0.0997	0.1762
Serious Event (Onset <= April 26, 2006)*	320	568	0.0124	324	533	0.0119	0.1655
Serious Event (Onset >= April 27, 2006)*	55	74	0.0010	57	68	0.0009	0.5407
Study Related Serious Event (Onset <= April 26, 2006)*	3	3	0.0001	2	2	0.0000	0.6426
Study Related Serious Event (Onset >= April 27, 2006)*	0	0	0.0000	0	0	0.0000	.

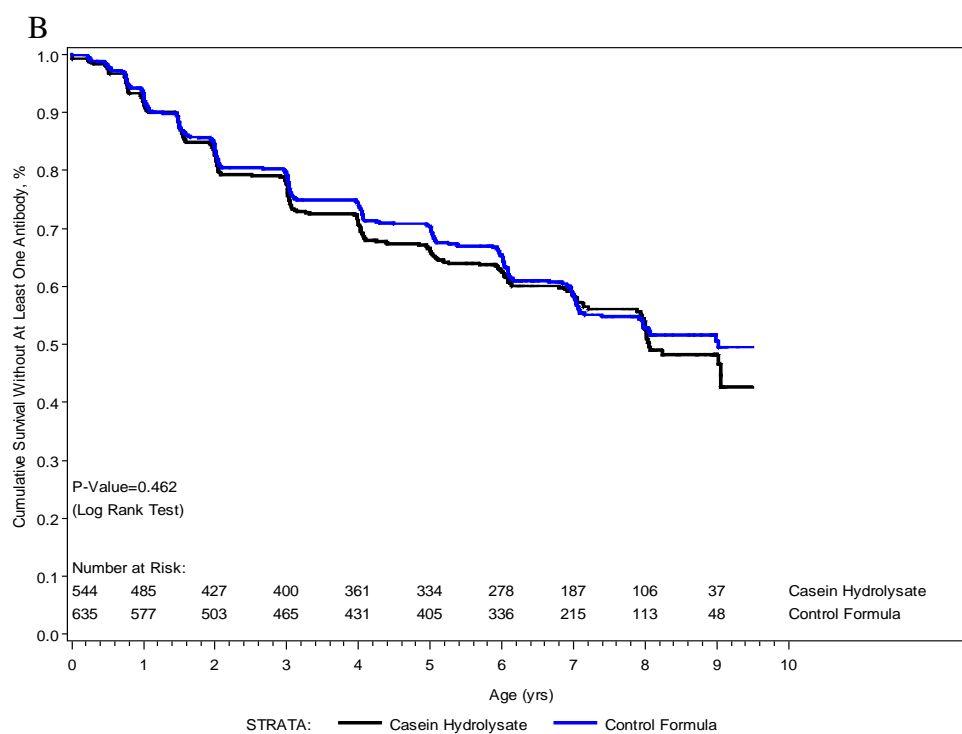
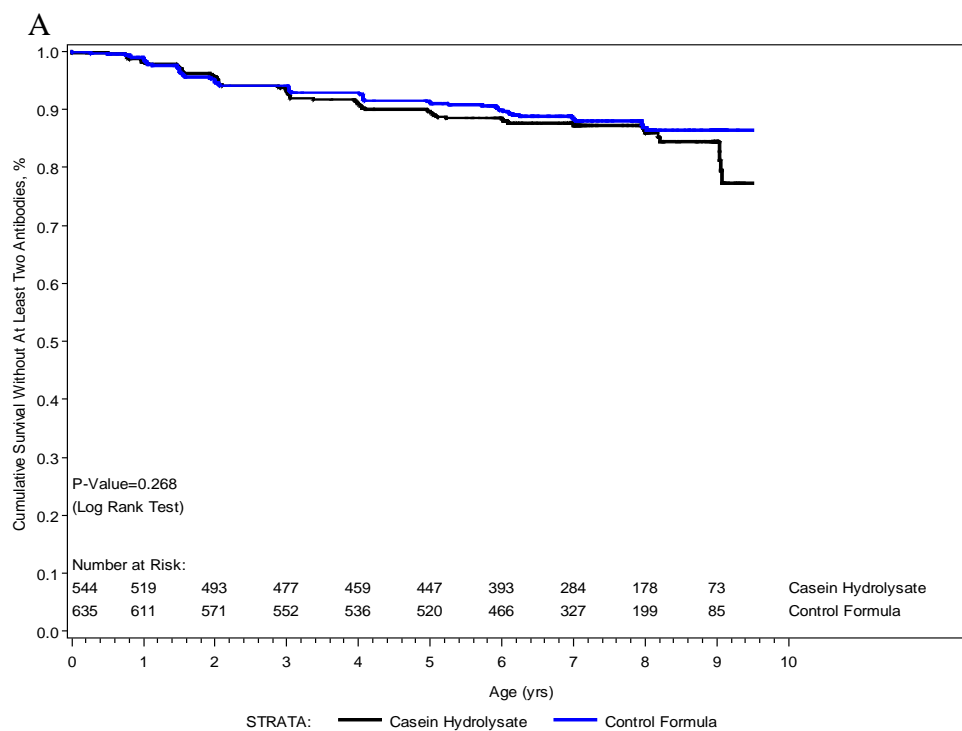
*Serious Event - Defined based on Date of Onset:

Onset <= April 26, 2006: Event of Malignancy, Accident (Requiring Hospitalization), or Death OR an Event Requiring either an Emergency Room Visit or Inpatient Hospital Visit

Onset >= April 27, 2006: Event of Malignancy, Accident (Requiring Hospitalization), Death, Requiring Inpatient Hospitalization or Prolongation of Existing Hospitalization, Life-Threatening, or Persistent or Significant Disability/Incapacity

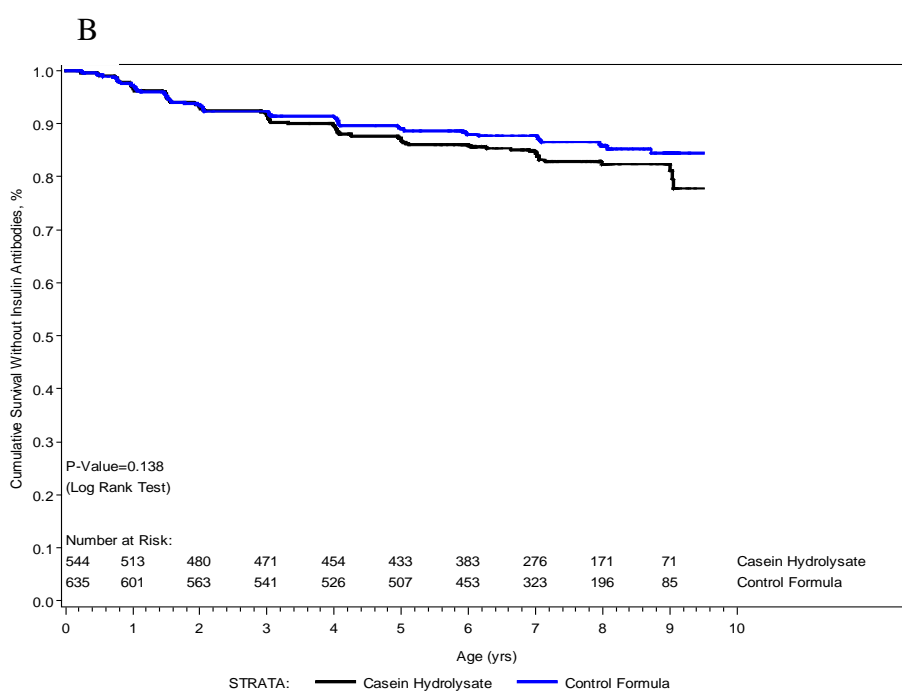
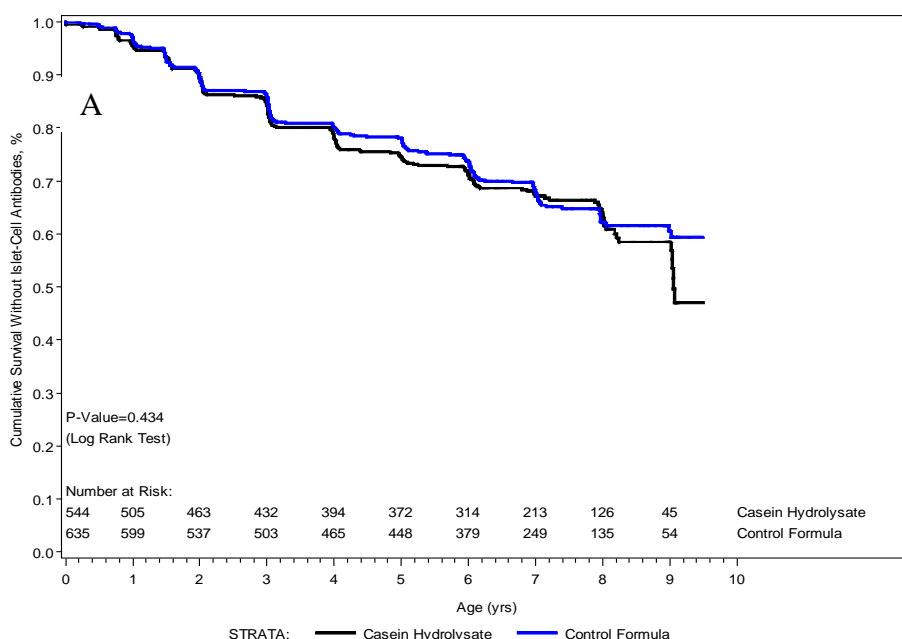
eFigure 1. Cumulative Survival Without Islet Cell Antibodies, Insulin Autoantibodies and Autoantibodies to Glutamic Acid Decarboxylase and the Insulinoma-Associated 2 Molecule (IA-2) in the 2 Study Groups According to the Per-Protocol Analysis

The cumulative survival without at least two autoantibodies (Panel A) and at least one autoantibody (Panel B) in the casein hydrolysate group and in the control group according to the age of the children at the time the autoantibodies were detected is shown.



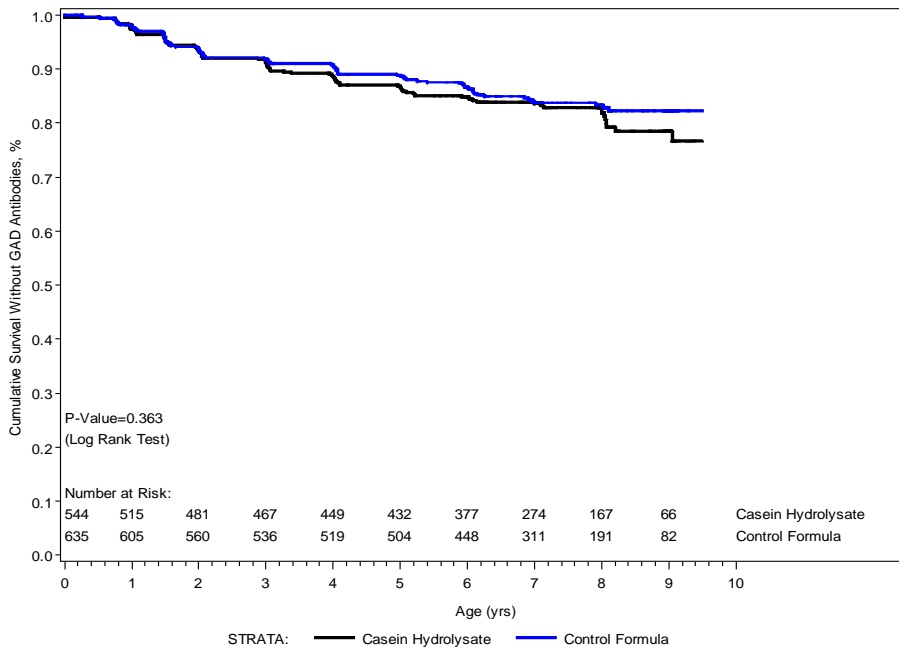
eFigure 2. Cumulative Survival Without Islet Cell Antibodies, Insulin Autoantibodies and Autoantibodies to Glutamic Acid Decarboxylase and the Insulinoma-Associated 2 Molecule (IA-2) in the 2 Study Groups According to the Per-Protocol Analysis

The cumulative survival without islet-cell antibodies (Panel A), insulin autoantibodies (Panel B), GAD antibodies (Panel C) and IA-2 autoantibodies (Panel D) in the casein hydrolysate group and in the control group according to the age of the children at the time the autoantibodies were detected is shown.

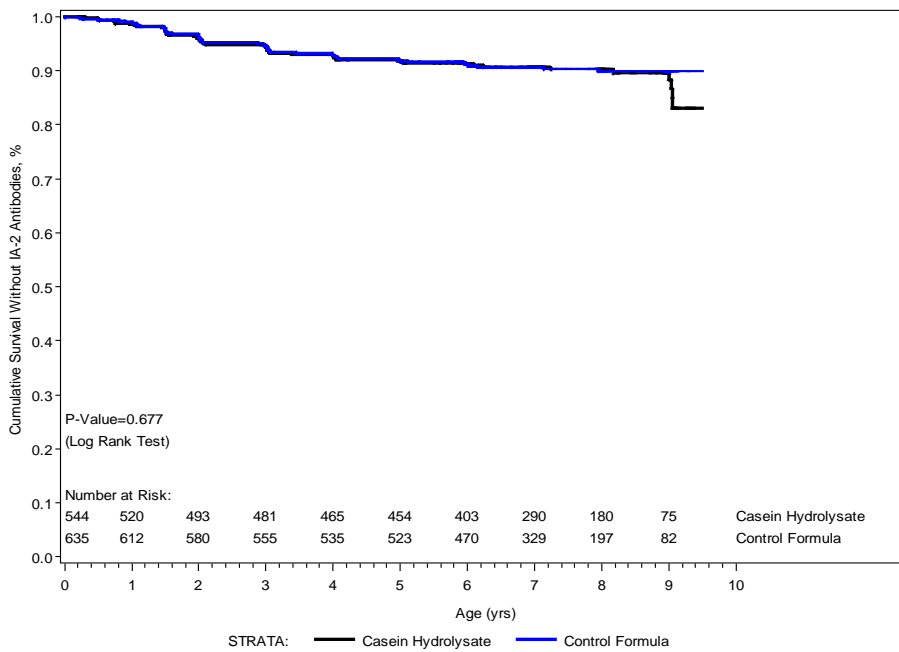


...continued eFigure 2.

C

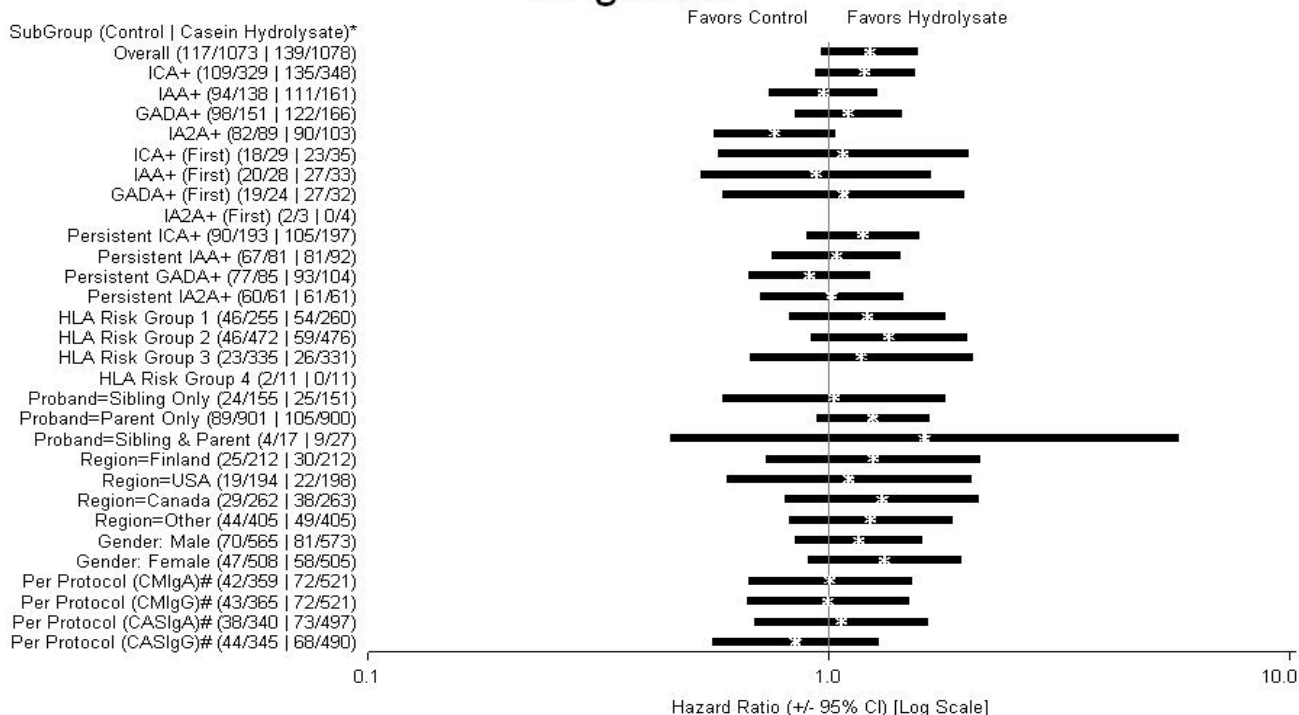


D



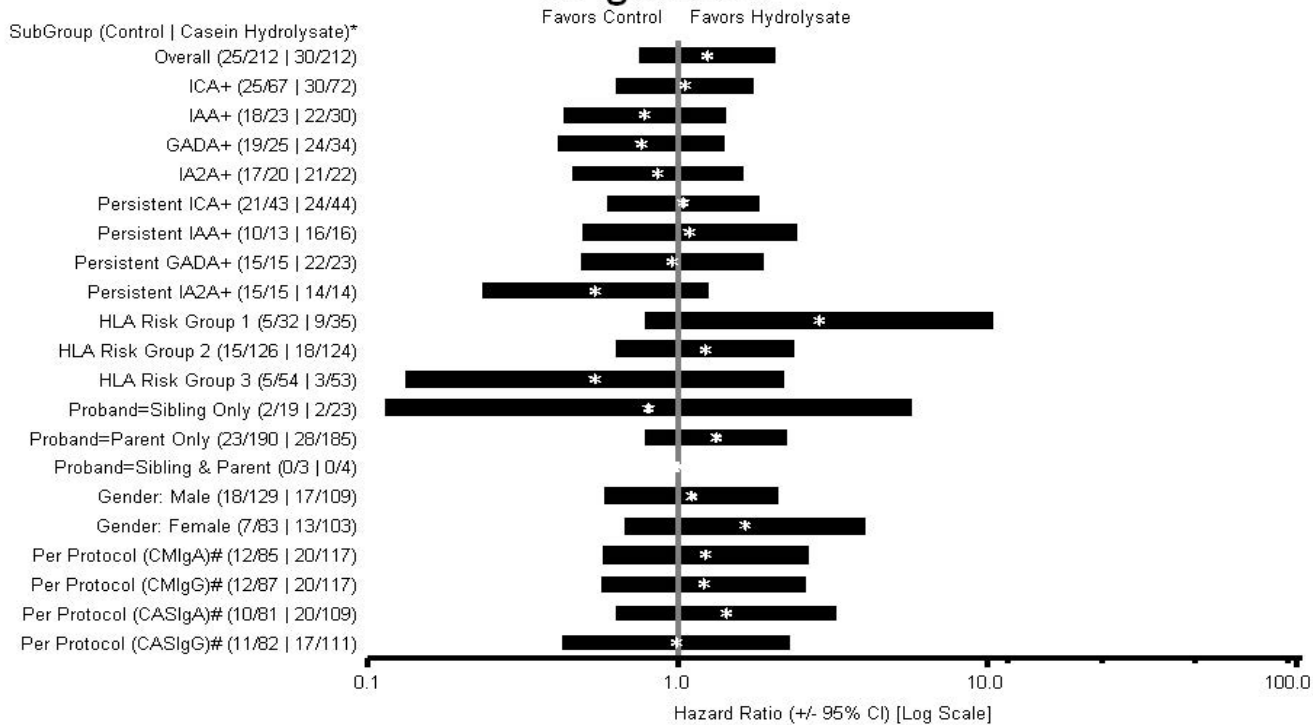
eFigure 3. Hazard Ratios (95% CI) for Subgroups in the Whole Trial (A) and for Subgroups Among the Finnish Participants According to the Per-Protocol Analysis (B)
 NC = not computable

eFigure 3A



* (N with Outcome/N in Subgroup) for each Treatment

eFigure 3B



* (N with Outcome/N in Subgroup) for each Treatment

* The numbers in parentheses refer to the number of children who had an event out of the total population in that subgroup.