

Funding agency certificate No. 1

Study title:

A study to observe correlation between resection and reconstruction procedures employed for gastric neoplasms and development of postgastrectomy syndrome

This study was conducted by Japan Postgastrectomy Syndrome Working Party and registered to the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR) as study #000002116.

This study was supported by a grant from The Jikei University School of Medicine.

I affirm that the above statements are completely correct.

Date *June 27, 2016*

President of The Jikei University School of Medicine

Senya Matsufuji, M.D., Ph.D.

Senya Matsufuji

Funding agency certificate No. 2

Study title:

A study to observe correlation between resection and reconstruction procedures employed for gastric neoplasms and development of postgastrectomy syndrome

This study was conducted by Japan Postgastrectomy syndrome working party and registered to UMIN-CTR #000002116.

This study was supported by a grant from Japanese Society for Gastro-surgical Pathophysiology.

I affirm that the above mentioned statements are completely correct.

Date

26/June/2016

The president of Japanese Society for Gastro-surgical Pathophysiology e

Yasuyuki Seto, M.D., Ph.D.

Yasuyuki Seto



UMIN-CTR Clinical Trial

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Name:	UMIN ID:
Recruitment status	Completed
Unique ID issued by UMIN	UMIN000002116
Receipt No.	R000002578
Official scientific title of the study	A study to observe correlation between resection and reconstruction procedures employed for gastric neoplasms and development of postgastrectomy syndrome
Date of disclosure of the study information	2009/06/25
Last modified on	2014/09/07

* This page includes information on clinical trials registered in UMIN clinical trial registered system.

* We don't aim to advertise certain products or treatments

Basic information	
Official scientific title of the study	A study to observe correlation between resection and reconstruction procedures employed for gastric neoplasms and development of postgastrectomy syndrome
Title of the study (Brief title)	A study to observe correlation between resection and reconstruction procedures employed for gastric neoplasms and development of postgastrectomy syndrome
Region	Japan

Condition	
Condition	Gastric cancer patients who underwent various types of gastrectomy (GIST patients who underwent gastric wedge resection are also included)
Classification by specialty	Gastrointestinal surgery
Classification by malignancy	Malignancy
Genomic information	NO

Objectives	
Narrative objectives ₁	To examine health related quality of life and degree of postgastrectomy syndrome among patients who underwent various types of gastrectomy and reconstruction procedures.
Basic objectives ₂	Others
Basic objectives -Others	To study usefulness and validity of a questionnaire, which has been developed by a nationwide study group to assess health related quality of life and degree of postgastrectomy syndrome among patients who underwent surgery for gastric neoplasms.
Trial characteristics ₁	Exploratory
Trial characteristics ₂	
Developmental phase	Not applicable

Assessment	
Primary outcomes	To examine the degree of generic QOL (SF-8), symptom specific QOL (GSRS), other abdominal symptoms, ingested amount, weight loss and satisfaction.
Key secondary outcomes	To investigate the correlation between above mentioned factors.

Base	
Study type	Observational

Study design	
Basic design	
Randomization	
Randomization unit	
Blinding	
Control	
Stratification	
Dynamic allocation	
Institution consi	

deration	
Blocking	
Concealment	

Intervention	
No. of arms	
Purpose of inter vention	
Type of interven tion	
Interventions/Co ntrol_1	
Interventions/Co ntrol_2	
Interventions/Co ntrol_3	
Interventions/Co ntrol_4	
Interventions/Co ntrol_5	
Interventions/Co ntrol_6	
Interventions/Co ntrol_7	
Interventions/Co ntrol_8	
Interventions/Co ntrol_9	
Interventions/Co ntrol_10	

Eligibility	
Age-lower limit	20 years-old <=
Age-upper limit	75 years-old >=
Gender	Male and Female
Key inclusion cri teria	The inclusion criteria are as follows: (1) Gastric cancer patients with pathologically confirmed stage IA or IB disease or patients with a GIST who underwent gastric wedge resection.

	(2) Patients who underwent gastrectomy for the first time. (3) Patients who were not treated with chemotherapy. (4) Patients without any recurrence or distant metastasis. (5) Patients with an interval of one year or longer after gastrectomy. (6) Physical status 0 or 1. (7) Fully capable of understanding and responding to the questionnaire. (8) Without any other disease or previous surgery which may influence the results of questionnaire more than gastrectomy. (9) Without any organ failure or mental disease. (10) Written informed consent with date and signature of the said person.
Key exclusion criteria	(1) Active dual malignancy. (2) Patients who underwent concomitant resection of other organ(s) due to another disease (co-resection equivalent to cholecystectomy being the exceptions). (3) Considered as unsuitable to participate in the study by a surgeon who is in charge.
Target sample size	5600

Research contact person	
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Sponsor

Institute	Department of Surgery, The Jikei University School of Medicine
Institute	
Department	

Funding Source

Organization	The Jikei University School of Medicine
Organization	
Division	
Category of Funding Organization	Other
Nationality of Funding Organization	Japan

Other related organizations

Co-sponsor	
Name of secondary funder(s)	Japanese Society for Gastro-surgical Pathophysiology

Secondary IDs

Secondary IDs	NO
Study ID_1	
Org. issuing International ID_1	
Study ID_2	
Org. issuing International ID_2	
IND to MHLW	

Institutions

Institutions	静岡県立静岡がんセンター（静岡県）、市立豊中病院（大阪府）、広島大学病院（広島県）、千葉県がんセンター（千葉県）、横浜市立市民病院（神奈川県）、愛知県がんセンター中央病院（愛知県）、東京慈恵会医科大学病院（東京都）、千葉大学病院（千葉県）、高知大学病院（高知県）、栃木県立がんセンター（栃木県）京都大学病院（京都府）、県立広島病院（広島県）、埼玉県立がんセンター（埼玉県）、山形県立中央病院（山形県）、名古屋大学病院（愛知県）、大阪厚生年金病院（大阪府）、
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川崎医科大学病院（岡山県）、函館五稜郭病院（北海道）、横浜市立大学附属市民総合医療センター（神奈川県）、帝京大学病院（東京都）、新潟県立がんセンター新潟病院（新潟県）、東京女子医科大学病院（東京都）、がん研有明病院（東京都）、岩手医科大学病院（岩手県）、JA広島総合病院（広島県）、東邦大学医療センター大橋病院（東京都）、岐阜市民病院（岐阜県）、大阪医科大学病院（大阪府）、福岡大学病院（福岡県）、神戸市立医療センター中央市民病院（兵庫県）、佐久市立国保浅間総合病院（長野県）、筑波大学病院（茨城県）、北野病院（大阪府）、札幌医科大学病院（北海道）、浜松医科大学病院（静岡県）、がん・感染症センター都立駒込病院（東京都）、原町赤十字病院（群馬県）、九州大学病院（福岡県）、鹿児島大学病院（鹿児島県）、金沢医科大学病院（石川県）、長崎医療センター（長崎県）、国際医療福祉大学三田病院（東京都）、久留米大学病院（福岡県）、大阪府済生会野江病院（大阪府）、京都医療センター（京都府）、大手前病院（大阪府）、東京女子医科大学東医療センター（東京都）、東京慈恵会医科大学柏病院（千葉県）、城山病院（大阪府）、大分大学病院（大分県）、東北大学病院（宮城県）、横須賀市立うわまち病院（神奈川県）

Other administrative information

Date of disclosure of the study information	2009 Year 06 Month 25 Day
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Progress

Recruitment status	Completed
Date of protocol fixation	2009 Year 04 Month 27 Day
Anticipated trial start date	2009 Year 07 Month 01 Day
Last follow-up date	2010 Year 12 Month 01 Day
Date of closure to data entry	2011 Year 02 Month 01 Day
Date trial data considered complete	2011 Year 04 Month 01 Day
Date analysis concluded	2012 Year 02 Month 01 Day

Related information

URL releasing protocol	
Publication of results	Published

sults	
URL releasing results	
Results	<p>1. Nakada K, Ikeda M, Takahashi M, et al. Characteristics and clinical relevance of postgastrectomy syndrome assessment scale (PGSAS)-45: newly developed integrated questionnaires for assessment of living status and quality of life in postgastrectomy patients. Gastric Cancer. 2014 Feb 11. [Epub ahead of print]</p> <p>2. Terashima M, Tanabe K, Yoshida M, et al. Postgastrectomy Syndrome Assessment Scale (PGSAS)-45 and Changes in Body Weight are Useful Tools for Evaluation of Reconstruction Methods Following Distal Gastrectomy. Ann Surg Oncol. 2014 Mar 4. [Epub ahead of print]</p> <p>3. Namikawa T, Hiki N, Kinami S, et al. Factors that minimize postgastrectomy symptoms following pylorus-preserving gastrectomy: assessment using a newly developed scale (PGSAS-45). Gastric Cancer. 2014 Apr 24. [Epub ahead of print]</p> <p>4. Takiguchi N, Takahashi M, Ikeda M, et al. Long-term quality-of-life comparison of total gastrectomy and proximal gastrectomy by Postgastrectomy Syndrome Assessment Scale (PGSAS-45): a nationwide multi-institutional study. Gastric Cancer. 2014 May 7. [Epub ahead of print]</p> <p>5. Misawa K, Terashima M, Uenosono Y, et al. Evaluation of postgastrectomy symptoms after distal gastrectomy with Billroth-I reconstruction using the Postgastrectomy Syndrome Assessment Scale-45 (PGSAS-45). Gastric Cancer. 2014 Aug 5. [Epub ahead of print]</p> <p>6. Inada T, Yoshida M, Ikeda M, et al. Evaluation of QOL After Proximal Gastrectomy Using a Newly Developed Assessment Scale (PGSAS-45). World J Surg. 2014 Aug 19. [Epub ahead of print]</p>
Other related information	To compare health related quality of life and degree of postgastrectomy syndrome among patients who underwent various types of gastrectomy and reconstruction procedures.

Management information	
Registered date	2009 Year 06 Month 24 Day
Last modified on	2014 Year 09 Month 07 Day

Link to view the page	
URL(English)	https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000002578

Research Plan		
Registered date	Registrant	File name

Research case data specifications		
Registered date	Registrant	File name

Research case data		
Registered date	Registrant	File name

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