# LOGICA trial

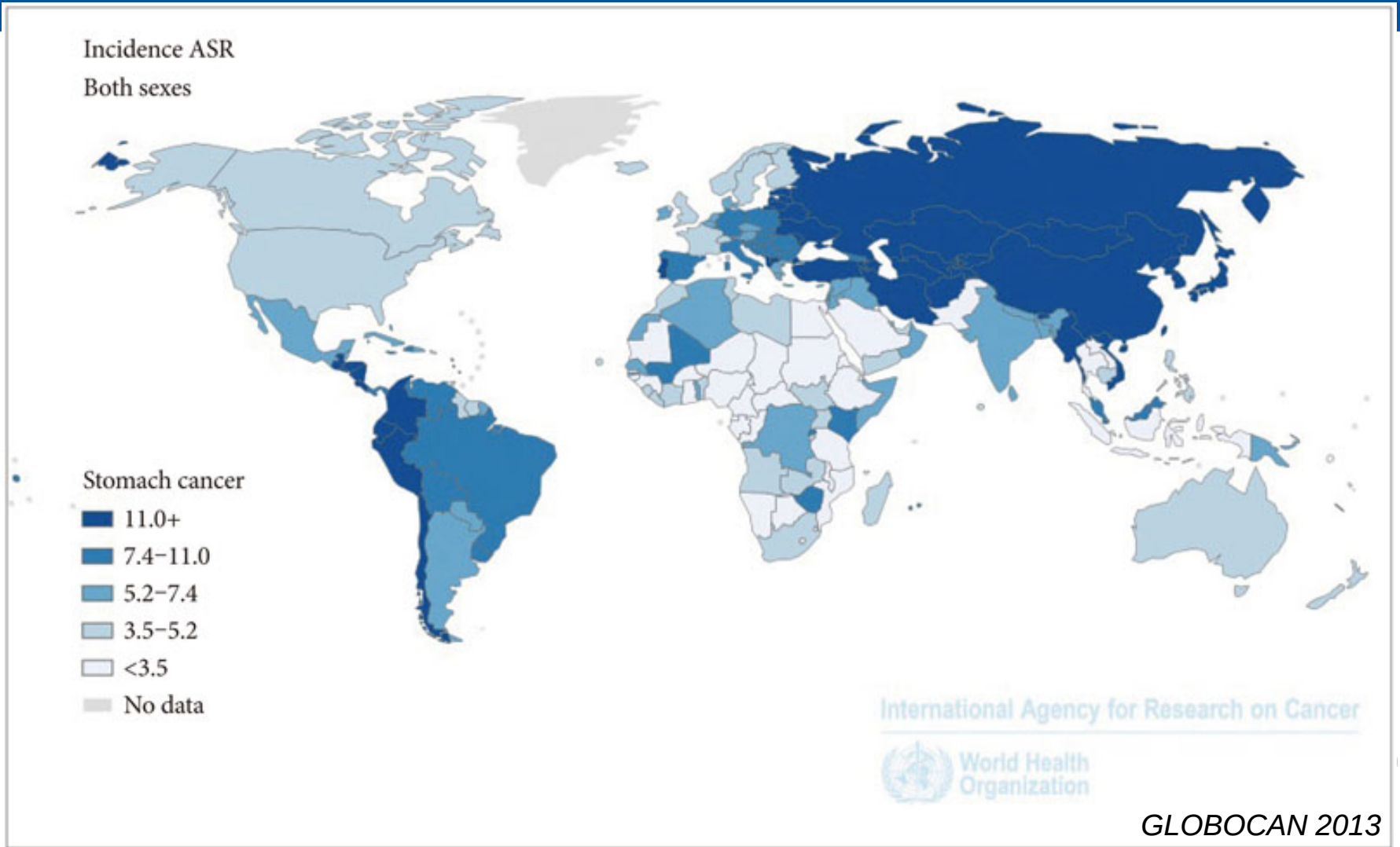
*"**L**aparoscopic versus **O**pen Gastrectomy for **G**astr**i**c **Ca**ncer – a multicenter prospectively randomized controlled trial"*

# Achtergrond

Nieuwe gevallen maagkanker

| | |
|---|---|
| Wereld | = 1 miljoen (5e) |
| Azië | = 0,5 miljoen |
| NL | = 1500 |

*Global Cancer Statistics 2012*
*Nederlandse Kankerregistratie*




GLOBOCAN 2013

# Achtergrond

- Diagnose maagkanker
  - 5-jaarsoverleving 20-25%

*Nederlandse Kankerregistratie*

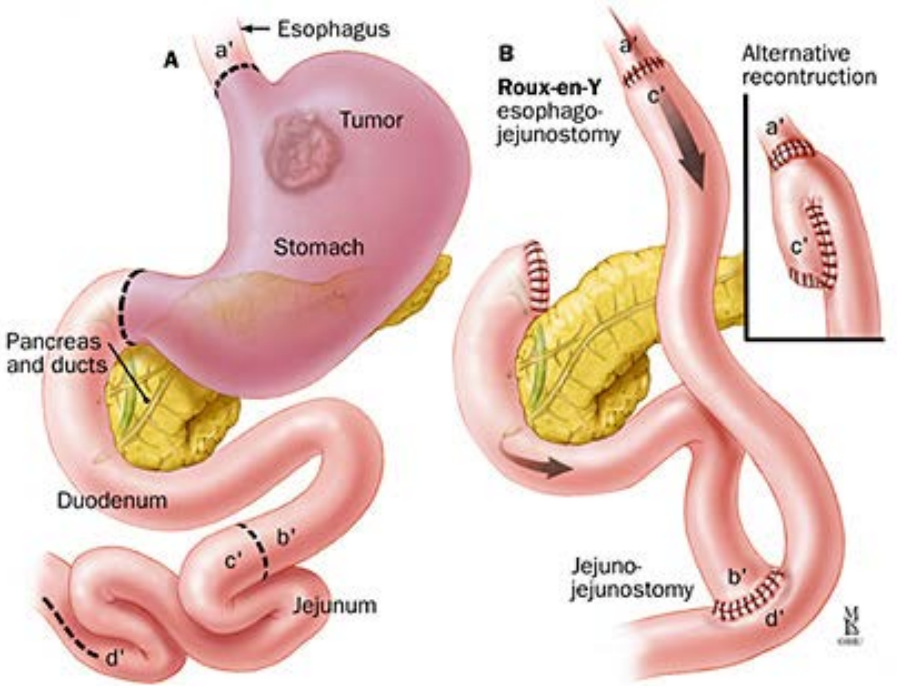
- Curatief (33%): Chirurgische resectie
  - 5-jaarsoverleving ~45%

*Hartgrink, J Clin Oncol 2004*

- Perioperatief chemotherapie
  - 5-jaarsoverleving + 10%

*Ronellenfitsch , Cochrane 2013.*

# Achtergrond




- Maagresectie
- Lymfeklierdissectie
- Reconstructie

Nederland (2013)

- 75 % Open
- 25 % Laparoscopisch

*DUCA 2013*

# Laparoscopie vs. Open

Meta-analyses

- Minder bloedverlies
- Minder complicaties
- Kortere ligduur
- Gelijke oncologische uitkomsten (R0, lymfeklieren, 5-jaars overleving)

Voornamelijk Aziatische studies:

- Hoge prevalentie
- Screening → Andere patientenpopulatie (tumorstadium, leeftijd)

*Haverkamp, Surg Endosc 2013*


*"**L**aparoscopic versus **O**pen Gastrectomy for **G**astr**i**c **Ca**ncer – a multicenter prospectively randomized controlled trial"*

# Doel

Het vergelijken van laparoscopische vs. open maagresectie

# Hypothese

Laparoscopische maagresectie:

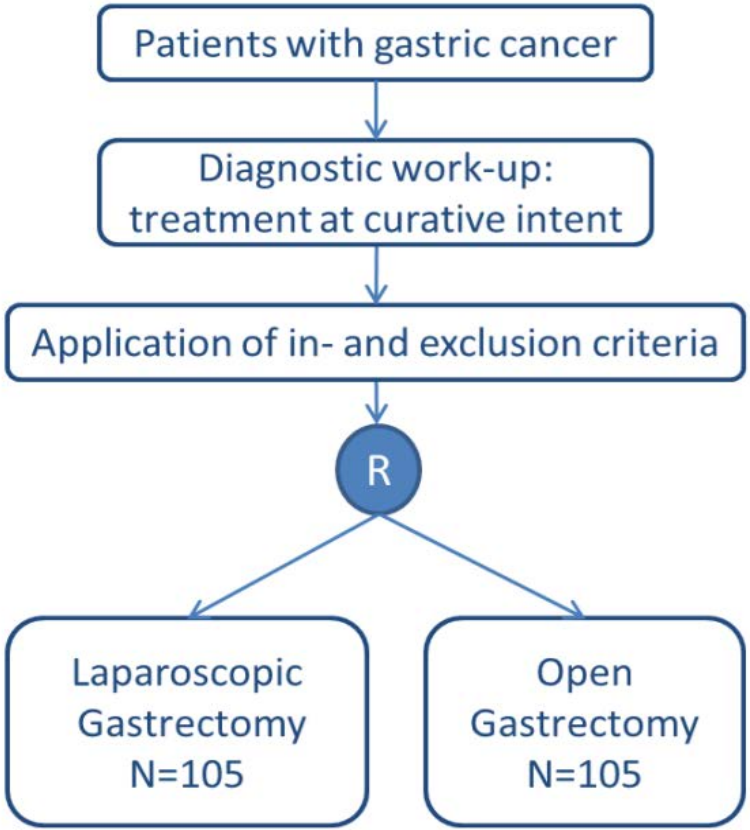
- een beter en sneller postoperatief herstel
- vergelijkbare oncologische uitkomsten

# In- en exclusie criteria

- Histologisch bewezen adenocarcinoom maag
- Chirurgisch resectabele tumor (cT1-4a,N0-3b,M0)
- Leeftijd ≥ 18
- European Clinical Oncology Group (ECOG) performance status 0,1 of 2
- Informed consent

- Siewert type I cardiacarcinoom
- Zwangerschap

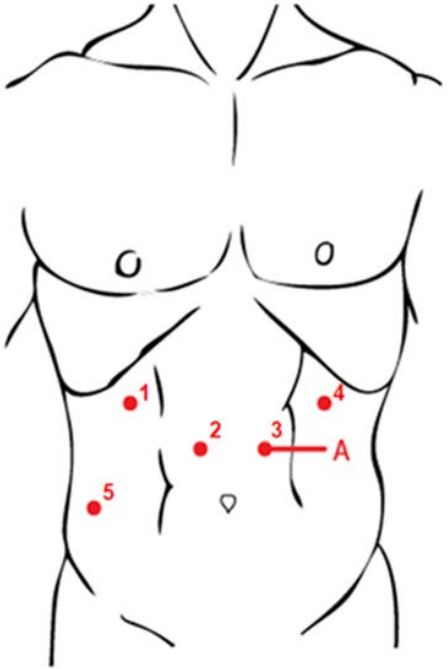
# Studie opzet




Totale + Distale maagresectie

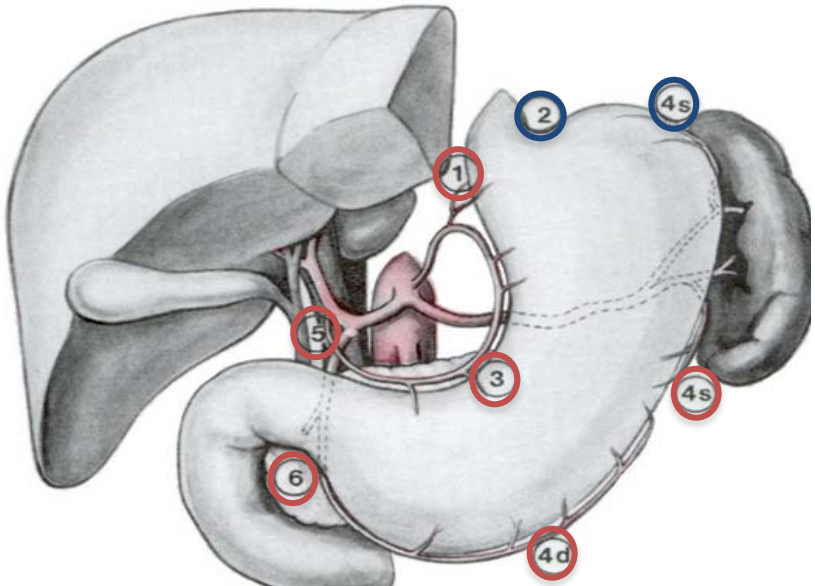
# Chirurgische procedure

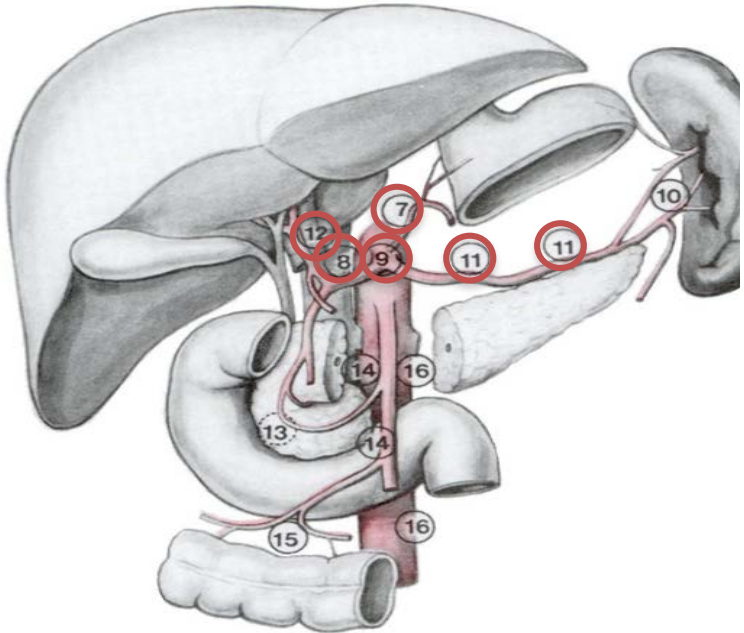
- Distale / totale maagresectie
- Roux-en-Y reconstructie
- Esophagojejunostomie
- Jejunumpouch optioneel



# Lymfeklierdissectie – D2

| Distal gastrectomy | | Total gastrectomy | |
|---|---|---|---|
| D1: | Station 1,3,4sb, 4d, 5, 6, 7 | D1: | Station 1-7 |
| D1+: | Station 1,3,4sb, 4d, 5, 6, 7, 8, 9 | D1+: | Station 1-7, 8, 9, 11p |
| D2: | Station 1,3,4sb, 4d, 5, 6, 7, 8, 9, 11p, 12a | D2: | Station 1-7, 8, 9, 11p, 11d, 12a |




| LN station number | |
|---|---|
| 1 | Right paracardial |
| 2 | Left paracardial |
| 3 | Lesser curvature |
| 4sa | Short gastric |
| 4sb | Left gastroepiploic |
| 4d | Right gastroepiploic |
| 5 | Surapyloric |
| 6 | Infrapyloric |
| 7 | Left gastric artery |
| 8a | Anterior common hepatic |
| 8b | Posterior common hepatic |
| 9 | Celiac artery |
| 10 | Splenic hilum |
| 11p | Proximal splenic |
| 11d | Distal splenic |
| 12a | Left hepatoduodenal |
| 12b,p | Post-hepatoduod |
| 13 | Retropancreatic |
| 14v | Superior mesenteric v. |
| 14a | Superior mesenteric a. |
| 15 | Middle colic |
| 16a1 | Aortic hiatus |
| 16a2,b1 | Paraaortic, middle |
| 16b2 | Paraaortic, caudal |
| 17 | Anterior pancreatic |
| 18 | Inferior pancreatic |
| 19 | Infradiaphragmatic |
| 20 | Esophageal hiatus |
| 110 | Lower paraesophag. |
| 111 | Supradiaphragmatic |
| 112 | Post-mediastinal |

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*ERAS guidelines, Mortensen et al BJS 2014*

# Perioperatief protocol

- Preoperatief bijvoeden: MUST score ≥2
- Epiduraal: Optioneel bij open
- Maagsonde: nee
- Buikdrain: nee
- Thoraxdrain: nee
- Jejunumfistel: nee
- Voeden: Start op dag 1 postoperatief

# Protocol: ERAS

| | Summary and recommendations | Evidence level | Recommendation grade |
|---|---|---|---|
| Wound catheters and TAP block | Evidence is conflicting regarding wound catheters in abdominal surgery | Wound catheters: Low to moderate | Weak |
| | Evidence is strong in support of TAP block in abdominal surgery in general, although the effect is evident only during the first 48 h after surgery and none of the evidence is from gastrectomies | TAP blocks: Low | Weak |
| Nasogastric/nasojejunal decompression | Nasogastric tubes should not be used routinely in the setting of enhanced recovery protocols in gastric surgery | High | Strong |
| Perianastomotic drains | Avoiding the use of abdominal drains may reduce drain-related complications and shorten hospital stay after gastrectomy | High | Strong |
| Early postoperative diet and artificial nutrition | Patients undergoing total gastrectomy should be offered drink and food at will from POD 1. They should be advised to begin cautiously and increase intake according to tolerance | Moderate | Weak |
| | Patients clearly malnourished or those unable to meet 60% of daily requirements by POD 6 should be given individualized nutritional support | Moderate | Strong |
| Audit | Systematic audit improves compliance and clinical outcomes | Low | Strong |

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# Primaire uitkomstmaat

- Postoperatieve ligduur

Ontslagcriteria:

- Adequate pijn controle met orale medicatie (VAS-score <5)
- Gestart met mobilisatie
- Adequate voedingsintake en onafhankelijk van intraveneuze vloeistoffen

# Secundaire uitkomstmaten

- Kosteneffectiviteit
- Oncologische uitkomsten (lymfeklieren, R0)
- Postoperatieve morbiditeit and mortaliteit
- Heropnames
- Kwaliteit van Leven (EQ-5D-5L, EORTC)
- Overleving

# Additionele metingen

| Pre-OK | Post-OK | |
|---|---|---|
| 2x Bloedafname (1  biobank) | Bloedafname | Direct postoperatief, POD 1 (& 2) |
| Biopsie (biobank) | VAS-score | POD 1 & 2 |
| KvL vragenlijsten | KvL vragenlijsten | 6 wkn & 6, 12, 24, 36, 48, 60 mnd |

- KvL : alle centra
- Bloedafname: alle centra
- Biobank: selectief









Rijnstate


Almelo

# Sample size

Op afname ligduur 18 → 14 dagen n = 210

# Haalbaarheid

Maagresecties 2013 (DUCA) x 40% inclusie n = 266

*Haverkamp, Surg Endosc 2013*
*DUCA*

"One day course on minimally invasive gastrectomy"

## General Information

| | |
|---|---|
| Date: | **March 14th 2014** |
| Target Group: | This day is set up for surgeons and OR nurses |
| Certification: | Dutch Society for Surgery |
| Accreditation: | 6 points by NVvH |
| Location: | Refereerruimte stafgang Heelkunde (G04.206)<br>UMC Utrecht<br>Heidelberglaan 100<br>3584 CX Utrecht<br>The Netherlands |
| Registration: | You can register by filling and return attached registration card or e-mail to r.liesdek@umcutrecht.nl |
| Registration fee: | Surgeons: € 175<br>OR nurses: € 50 |

The registration fee can be paid to the account number of the Stichting Chirurgische Oncologie Utrecht: ING 5270359 stating Gastric day UMCU.

| | |
|---|---|
| Information: | Department of Surgery, UMC Utrecht |
| Tel: | +31 (0)88-7558074 |
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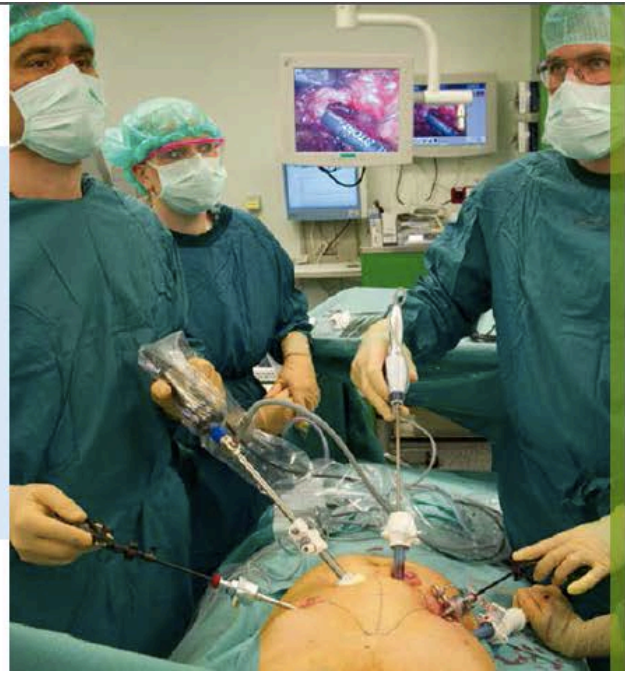
| Supported by: | Covidien, Storz, Nycomed |

COVIDIEN

STORZ KARL STORZ—ENDOSKOPE

Takeda



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# Subsidies



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