



# ACST-2 Collaborators Meeting

22<sup>nd</sup> September 2020



# Where are we?



- As of today (22<sup>nd</sup> Sept 2020) **3591** patients recruited
- Recruitment continues until 31st Dec 2020
- 128 active centres from 33 countries
- Some patients are now in their 10<sup>th</sup> year of follow-up

# Quality of data continues to be good!

All Forms as of 22<sup>nd</sup> Sept 2020

<b>Total Randomised patients</b>	<b>Consent Form Received</b>	<b>Randomisation Form Received</b>	<b>1-month Follow-up Received</b>	<b>2019 Annual Follow-Received</b>
3591	3529 (98.4%)	3543 (98.8%)	3561 (99.3% )	2158 (82.3%)



# Missing Data



- **Consent Forms:** 46 /3591 from 23 sites
- **Randomisation Forms:** 32/3587 from 20 sites
- **1 Month Follow up Forms:** 77/3561, from 17 sites
- **Annual Follow Up Forms:** 470/2623 from 76 sites
- (24 patients are missing initial forms but do have annual follow up reported, of these 16 are only missing 1 form)

**Please continue to send the missing forms!**



# Missing Data



<b>No. of Initial Missing Forms</b>	<b>No. of patients with missing forms</b>
All 3	46
2	44
1	108



# Annual Follow Up 2019



- 82.3% received
- 470 still missing (121 from patients, 349 from sites)

We are now sending out **2020 Annual Follow Forms** –  
please send these back as soon as possible

**Thank you**



# RESTENOSIS AND MRI SUBSTUDIES



# Restenosis Data Collection



## Number of years of follow up

No. of Years of Follow Up	Percentage of Patients (n)
2	11.3% (406)
3	9.9% (354)
4	8.3% (298)
5+	43.4% (1556)
<b>Total with 2+</b>	<b>72.9% (2614)</b>





# Restenosis Data Collection



Sites who reported Doppler scans are done annually

Country	No. of Sites	% of Patients	Country	No. of Sites	% of Patients
Austria	1	1.7%	Hungary	1	3.1%
Belgium	2	2.2%	Israel	1	0.5%
Brazil	1	2.0%	Italy	14	18.1%
Canada	1	1.1%	Japan	1	0.2%
Croatia	2	0.4%	Poland	1	0.6%
Czech Rep	2	2.7%	Russia	2	0.8%
Egypt	1	0.06%	Serbia	2	9.0%
France	1	0.9%	Sweden	1	0.9%
Germany	7	5.6%	Switzerland	2	2.1%
Greece	2	2.9%	Netherlands	2	2.0%

47 centres are able to contribute data immediately (representing 57% of enrolled patients)



# 1 Duplex scan per patient



- Scan done 5 years (or ideally  $\geq 2$  years after treatment)
- Patients randomised before 1.1.2019
- Routine surveillance scans
  - Do not report scans done for workup after stroke or TIA
  - In patients with re-do CAS or CEA: report last scan before re-do treatment



NIHR HTA/BUPA Foundation/University of Oxford

# Asymptomatic Carotid Surgery Trial (ACST-2)



## Ultrasound Follow-up Form

Study ID: \_\_\_\_\_

Date of examination (day/month/year): /

**Left**

**Right**

PSV (CCA)=  cm/s PSV (CCA)=  cm/s

PSV (ICA)=  cm/s PSV (ICA)=  cm/s

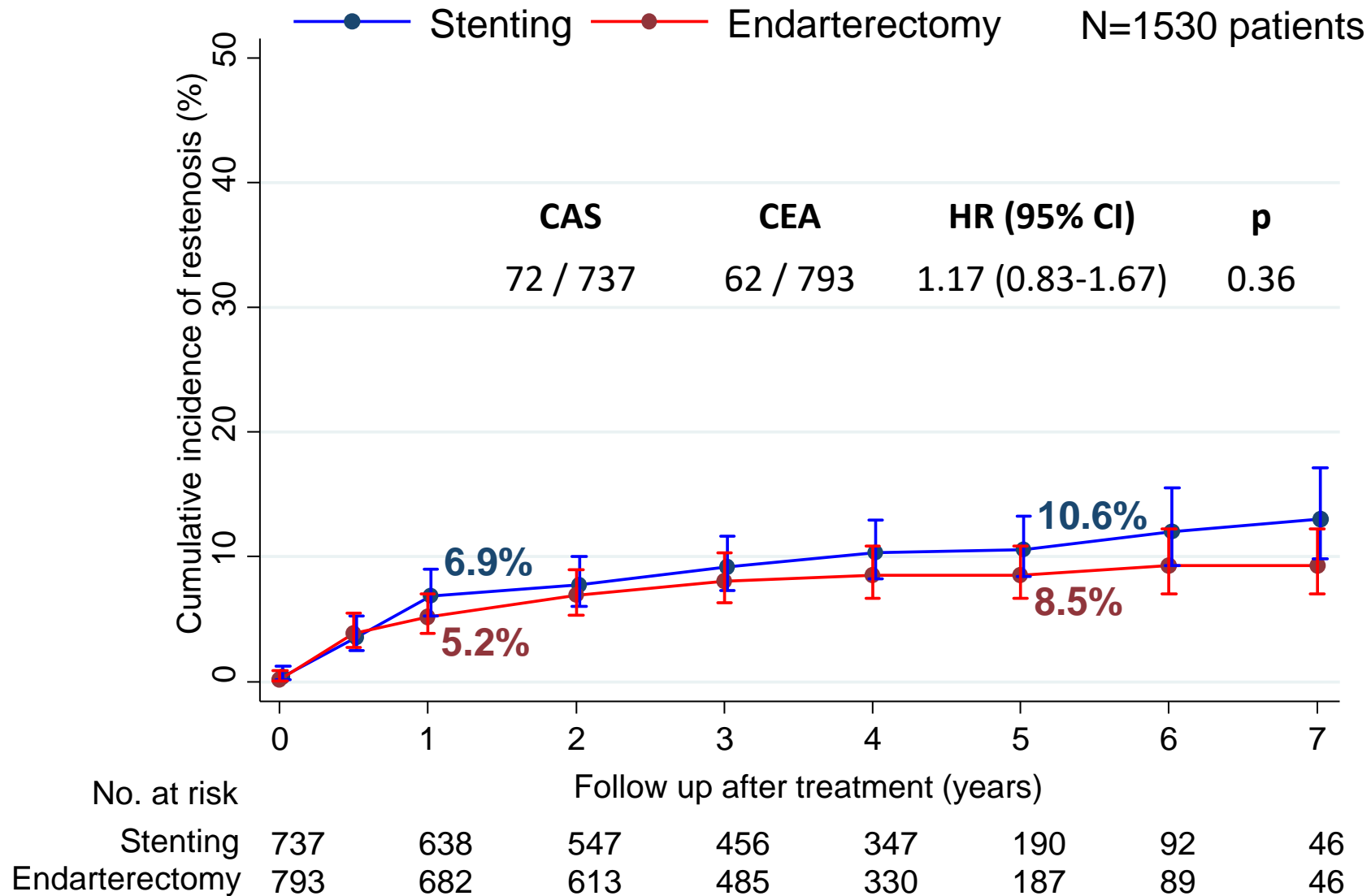
EDV (ICA)=  cm/s EDV (ICA)=  cm/s

*Please report sonographer's estimate of degree of ICA stenosis (according to NASCET criteria). **Please enter 100% if ICA is occluded***

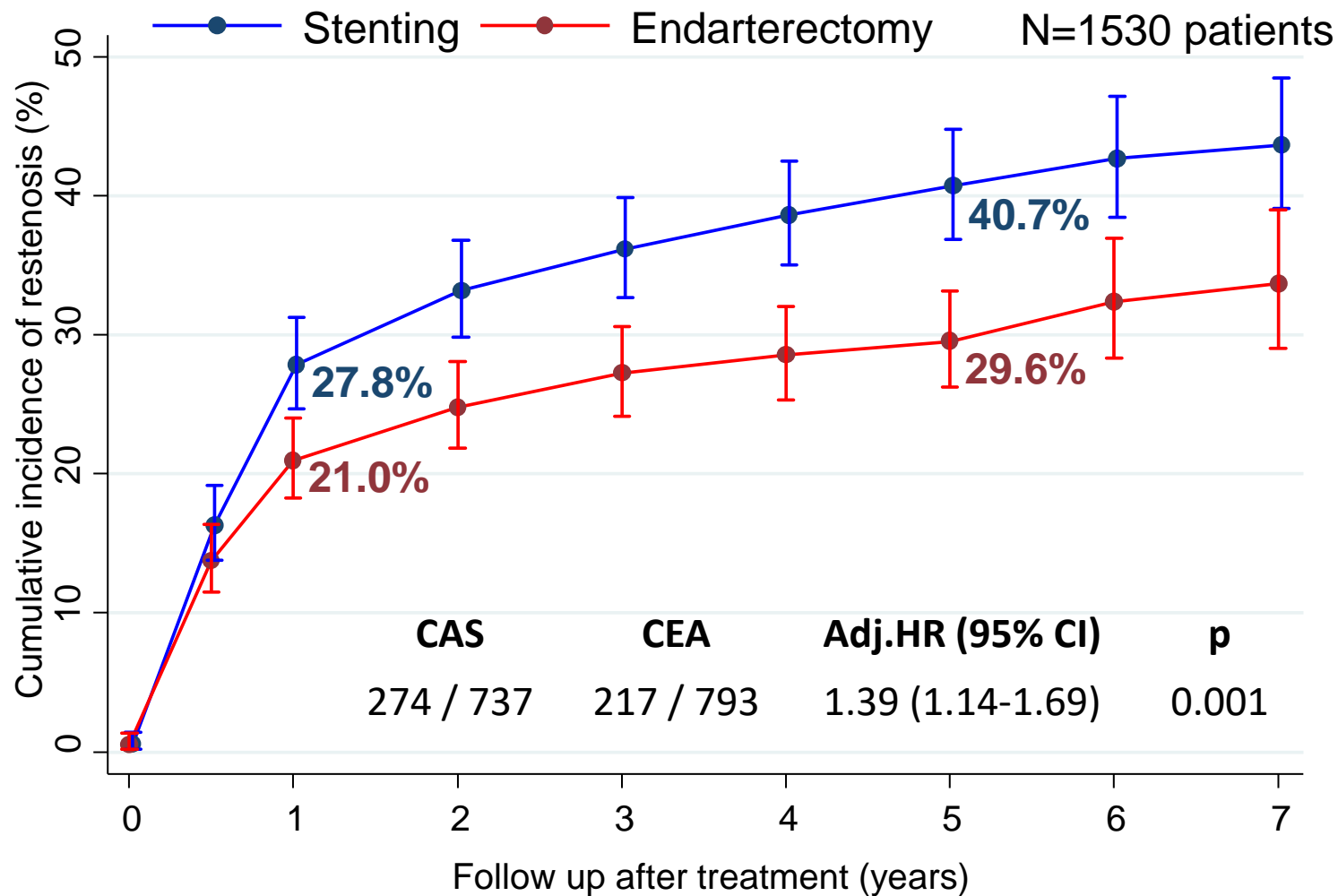
Left ICA: \_\_\_\_%

Right ICA: \_\_\_\_%

## ICSS: Severe ( $\geq 70\%$ ) restenosis or occlusion



## ICSS: Moderate ( $\geq 50\%$ ) or higher restenosis



CAS	CEA	Adj.HR (95% CI)	p
274 / 737	217 / 793	1.39 (1.14-1.69)	0.001

No. at risk		0	1	2	3	4	5	6	7
Stenting	737	496	407	333	245	137	63	33	
Endarterectomy	793	568	502	399	269	149	70	36	

# ACST-2 MRI Substudy

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## Reminder and update

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*Benjamin Wagner*

*Leo Bonati*

*Department of Neurology and Stroke Center,  
University Hospital Basel, Switzerland*

# Participating centres & enrolment

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- Active centres:
  - ❖ University Hospital Basel (CH): **60**
  - ❖ University Hospital of Larissa (GR): **32**
  - ❖ UMC Utrecht (NL): **22**
  - ❖ Serbian Clinical Centre Belgrade (RS): **11**
  - ❖ Istituto Auxologico Milano (IT): **11**
  - ❖ Klinikum rechts der Isar München (DE): **8**
  - ❖ La Sapienza Rome (IT): **6**

**150 patients** are currently enrolled

**135 patients** are in the SecuTrial

# Participating centres & enrolment

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Patient	Eligibility	Visit 0	Treatment	Visit 1	Visit 2	Visit 3	Study Termination	Adverse Events
BIOPLQ-BG033								
BIOPLQ-BG059								
BIOPLQ-BG071								
BIOPLQ-BG996								

- Please complete data entry for all your patients
- Only patients with complete data entry can be used for analysis
  - Please send us your MR images via CD



# Log for patients not included in substudy

**New patient**

Select a project: < Please choose >  
ACST-2 patients not included in MRI substudy (1.0.1)  
BIO-PLAQUE (1.5.6)

Patient was randomised to	<input type="radio"/> CAS <input checked="" type="radio"/> CEA
Any contraindication to MRI ...	<input checked="" type="radio"/> yes <input type="radio"/> no <input type="radio"/> unknown
... including	<input type="checkbox"/> Claustrophobia <input checked="" type="checkbox"/> Metal implant incompatible with MRI <input type="checkbox"/> Cardiac pacemaker incompatible with MRI <input type="checkbox"/> Other
Patient does not consent to MRI	<input type="radio"/> yes <input checked="" type="radio"/> no
MRI scanner unavailable <u>before</u> treatment	<input type="radio"/> yes <input type="radio"/> no <input checked="" type="radio"/> unknown
MRI scanner unavailable <u>after</u> treatment	<input type="radio"/> yes <input type="radio"/> no <input checked="" type="radio"/> unknown
Other reasons	<input type="radio"/> yes <input checked="" type="radio"/> no

Please enter required data for all your ACST-2 patients **NOT included** in the MRI substudy at your centre (reasons for exclusion)



# ACST2 Future Plans



## ESVS 2021: Belfast

