UMIN-CTR Clinical Trial

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Name: **UMIN ID:**

Recruitment status	No longer recruiting
Unique ID issued by UMIN	UMIN000028694
Receipt No.	R000032809
Scientific Title	A prospective study on colon capsule endoscopy using caster oil
Date of disclosure of the study information	2017/08/31
Last modified on	2020/02/17

* This page includes information on clinical trials registered in UMIN clinical trial registed system.
* We don't aim to advertise certain products or treatments

Basic information	
Public title	A prospective study on colon capsule endoscopy using caster oil
Acronym	A prospective study on colon capsule endoscopy using caster oil
Scientific Title	A prospective study on colon capsule endoscopy using caster oil
Scientific Title:Acronym	A prospective study on colon capsule endoscopy using caster oil
Region	Japan

Condition	
Condition	Colon disease
Classification by specialty	Gastroenterology
Classification by malignancy	Others
Genomic information	NO

Objectives	
Narrative objectives 1	The aim of this study is to use castor oil as a booster for colon capsule endoscopy and to verify capsule excretion rate, transit time of capsule excretion, and bowel cleansing level.
Basic objectives2	Safety,Efficacy
Basic objectives -Others	
Trial characteristics_	

1	
Trial characteristics_2	
Developmental phase	

Assessment	
Primary outcomes	capsule excretion rate, transit time of capsule excretion, bowel cleansing level
Key secondary outcomes	

Base	
Study type	Interventional

Study design	
Basic design	Single arm
Randomization	Non-randomized
Randomization unit	
Blinding	Open -no one is blinded
Control	Uncontrolled
Stratification	
Dynamic allocation	
Institution consideration	
Blocking	
Concealment	

Intervention	
No. of arms	1
Purpose of intervention	Diagnosis
Type of intervention	Medicine
Interventions/Control_1	Caster Oil
Interventions/Control_2	
Interventions/Control_3	
Interventions/Contr	

ol_4	
Interventions/Control_5	
Interventions/Control_6	
Interventions/Control_7	
Interventions/Control_8	
Interventions/Control_9	
Interventions/Control_10	

Eligibility	
Age-lower limit	16 years-old <=
Age-upper limit	80 years-old >
Gender	Male and Female
Key inclusion criteria	Patients with confirmed or suspicious of harboring colorectal disease
Key exclusion criteria	Patients with dysphasia Patients with allergy to drugs used in this study Pregnant or possible pregnant women Patients who undergo MRI 2 weeks after CCE Patients with present or past history of small and large bowel obstruction Patients suspicious of having colorectal advanced carcinoma by tumor markers or symptoms Patients inappropriate for this study by other reasons judged by investigators
Target sample size	20

Research contact person	
Name of lead principal investigator	**1st name** **Middle name** **Last name** Yoriaki Komeda
Organization	Kindai University Faculty of Medicine
Division name	Gastroenterology and Hepatology
Zip code	
Address	377-2 Ohno-higashi, Osaka-sayama
TEL	072-366-0221
Email	y-komme@mvb.biglobe.ne.jp

Public contact	

Name of contact person	**1st name** **Middle name** **Last name** Yoriaki Komeda
Organization	Kindai University Faculty of Medicine
Division name	Gastroenterology and Hepatology
Zip code	
Address	377-2 Ohno-higashi, Osaka-sayama
TEL	072-366-0221
Homepage URL	
Email	y-komme@mvb.biglobe.ne.jp

Sponsor	
Institute	Kindai University
Institute	
Department	

Funding Source	
Organization	Self funding
Organization	
Division	
Category of Funding Organization	Self funding
Nationality of Funding Organization	

Other related organizations	
Co-sponsor	
Name of secondary funder(s)	

IRB Contact (For public release)	
Organization	
Address	
Tel	
Email	

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	

Other administrative information	
Date of disclosure of the study information	2017 Year 08 Month 31 Day

Related information	
URL releasing protocol	
Publication of results	Unpublished

Result	
URL related to results and publications	
Number of participants that the trial has enrolled	
Results	
Results date posted	
Results Delayed	
Results Delay Reason	
Date of the first journal publication of results	
Baseline Characteristics	
Participant flow	
Adverse events	
Outcome measures	

Plan to share IPD	
IPD sharing Plan description	

Progress	
Recruitment status	No longer recruiting
Date of protocol fixation	2017 Year 07 Month 01 Day
Date of IRB	2017 Year 08 Month 28 Day
Anticipated trial start date	2017 Year 08 Month 31 Day
Last follow-up date	2019 Year 08 Month 31 Day
Date of closure to data entry	2019 Year 08 Month 31 Day
Date trial data considered complete	
Date analysis concluded	

Other	
Other related information	

Management information	
Registered date	2017 Year 08 Month 16 Day
Last modified on	2020 Year 02 Month 17 Day

Link to view the page	
URL(English)	https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000032809

Research Plan	
Registered date	**File name**

Research case data specifications	
Registered date	**File name**

Research case data	
Registered date	**File name**

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