# UMIN-CTR Clinical Trial

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**Name:** **UMIN ID:**

| | |
|---|---|
| **Recruitment status** | Enrolling by invitation |
| **Unique ID issued by UMIN** | UMIN000030539 |
| **Receipt No.** | R000034862 |
| **Official scientific title of the study** | Clinical usefulness of second generation colon capsule endoscopy (CCE-2) in patients with ulcerative colitis |
| **Date of disclosure of the study information** | 2017/12/24 |
| **Last modified on** | 2017/12/24 |

* 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 | |
|---|---|
| Official scientific title of the study | Clinical usefulness of second generation colon capsule endoscopy (CCE-2) in patients with ulcerative colitis |
| Title of the study (Brief title) | Clinical usefulness of colon capsule endoscopy in patients with ulcerative colitis |
| Region | Japan |

| Condition | |
|---|---|
| Condition | Patient with ulcerative colitis |
| Classification by specialty | Gastroenterology |
| Classification by malignancy | Others |
| Genomic information | NO |

| Objectives | |
|---|---|
| Narrative objectives1 | To clarify the clinical usefulness, safety, and compliance of second generation colon capsule endoscopy (CCE-2) in patients with ulcerative colitis.<br>To examine whether the severity of mucosal inflammation by CCE-2 is associated with thereafter bad outcome such as clinical relapse. |
| Basic objectives2 | Safety,Efficacy |
| Basic objectives -Others | |
| Trial characteristics_1 | |
| Trial characteristics_2 | Pragmatic |
| Developmental phase | Not applicable |

| Assessment | |
|---|---|
| Primary outcomes | 1. The rate of total colon observation within its battery life, and transit time<br>2. Severity of mucosal inflammation in clinical remission assessed by CCE using Mayo endoscopic subscore (Mayo ES) and Ulcerative Colitis Endoscopic Index of Severity (UCEIS) |

| | |
|---|---|
| Key secondary outcomes | 1. Cleansing level with a 4-point grading scale (poor, fair, good, and excellent)<br>2. Adverse events<br>3. Relapse-free survival, Exacerbation-free survival, surgery-free survival<br>4. Acceptability of CCE assessed by questionnaire survey. |

| Base | |
|---|---|
| Study type | Observational |

| Study design | |
|---|---|
| Basic design | |
| Randomization | |
| Randomization unit | |
| Blinding | |
| Control | |
| Stratification | |
| Dynamic allocation | |
| Institution consideration | |
| Blocking | |
| Concealment | |

| Intervention | |
|---|---|
| No. of arms | |
| Purpose of intervention | |
| Type of intervention | |
| Interventions/Control_1 | |
| Interventions/Control_2 | |
| Interventions/Control_3 | |
| Interventions/Control_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 | 1. Patients with known ulcerative colitis<br>Category A: outpatient, in clinical remission defined as the Rachmilewitz index of 0-4 points<br>Category B: active inpatient<br><br>2. Written informed consent |
| Key exclusion criteria | 1. Patients with dysphagia<br>2. Pregnant or possible pregnant women<br>3. Patients with a pacemaker or other implanted electromedical device<br>4. Patients with present or past history of small and large bowel obstruction<br>5. Patients with a contraindication to bowel preparation (congestive heart failure, renal insufficiency, a life-threatening condition)<br>6. Patients with an allergy to polyethylene glycol, magnesium citrate, sennoside, metoclopramide or mosapride citrate<br>7. Patients who will undergo MRI 2 weeks after CCE<br>8. Patients inappropriate for this study by other reasons judged by investigators |
| Target sample size | 50 |

| Research contact person | |
|---|---|
| Name of lead principal investigator | Satoshi Osawa |
| Organization | Hamamatsu University School of Medicine |
| Division name | Department of Endoscopic and Photodynamic Medicine |
| Address | 1-20-1 Handayama, Higashi-ku, Hamamatsu, 431-3192, Japan. |
| TEL | +81-53-435-2261 |
| Email | sososawa@hama-med.ac.jp |

| Public contact | |
|---|---|
| Name of contact person | Satoshi Osawa |
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| TEL | +81-53-435-2261 |
| Homepage URL | |
| Email | sososawa@hama-med.ac.jp |

| Sponsor | |
|---|---|
| Institute | Hamamatsu University School of Medicine |
| Institute | |
| Department | |

| Funding Source | |
|---|---|
| Organization | Department of Endoscopic and Photodynamic Medicine, Hamamatsu University School of Medicine |
| Organization | |
| Division | |

| | |
|---|---|
| Category of Funding Organization | Self funding |
| Nationality of Funding Organization | |

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

| 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 | 浜松医科大学医学部附属病院（静岡県）/Hamamatsu University Hospital |

| Other administrative information | |
|---|---|
| Date of disclosure of the study information | 2017 Year 12 Month 24 Day |

| Progress | |
|---|---|
| Recruitment status | Enrolling by invitation |
| Date of protocol fixation | 2015 Year 10 Month 01 Day |
| Anticipated trial start date | 2015 Year 10 Month 01 Day |
| Last follow-up date | 2018 Year 12 Month 31 Day |
| Date of closure to data entry | |
| Date trial data considered complete | |
| Date analysis concluded | |

| Related information | |
|---|---|
| URL releasing protocol | |
| Publication of results | Unpublished |
| URL releasing results | |

| | |
|---|---|
| Results | |
| Other related information | consecutive cases, prospective study<br>Actual study start date: October 2015<br>now registering |

| Management information | |
|---|---|
| Registered date | 2017 Year 12 Month 24 Day |
| Last modified on | 2017 Year 12 Month 24 Day |

| Link to view the page | |
|---|---|
| URL(English) | https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000034862 |

| 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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