

Hong Kong Baptist University to initiate Ph II trial for herbal drug to treat ulcerative colitis

04 September 2024 | News

To launch a randomised, double-blind, and placebo-controlled clinical trial in the Mainland in 2025



The Centre for Chinese Herbal Medicine Drug Development (CDD) at Hong Kong Baptist University (HKBU) has achieved a significant milestone in developing a novel Chinese herbal formulation for ulcerative colitis remission maintenance.

Following a submission of Investigational New Drug application for CDD-2103 to the National Medical Products Administration (NMPA) in mid-June this year, CDD has received in late August its authorisation for clinical trial.

CDD plans to commence a Phase II clinical trial for this new drug in the Mainland next year to verify its effectiveness and safety as a treatment for remission maintenance for ulcerative colitis.

In search of more effective ways to relieve ulcerative colitis, the research team developed a Chinese herbal formulation CDD-2103, with nine Chinese herbal medicines including Codonopsis Radix (dang shen) and Curcumae Longae Rhizoma (jiang huang), based on years of clinical experience. CDD-2103 is formulated for to maintain remission in ulcerative colitis patients who exhibit symptoms of spleen deficiency and internal accumulation of damp heat.

"It is anticipated that the larger scales of clinical trials will be completed in the next five years in order to confirm CDD-2103's therapeutic effect and safety in treating ulcerative colitis. After collecting sufficient data regarding the drug's safety and efficacy, the Centre will submit an application for NMPA's new drug approval, with the objective of obtaining authorisation for the sales of CDD-2103 in the market", said the researchers.