

## A series of registry studies on safety surveillance of seven post-marketing Chinese medicine injections in mainland China: Protocol

**Xing Liao**

China Academy of Chinese Medical Sciences, China

This study is supported by National Science and Technology Major Projects for 'Major New Drugs Innovation and Development'. Kudiezi injection's protocol will be taken as an example out of the seven Chinese Medicine injections in this abstract. Kudiezi injection (KDZI) is a kind of Traditional Chinese herbal extract, which is used to treat coronary heart disease and cerebral infarction in China.

**Objective:** to calculate the incidence of KDZI's adverse drug reaction (ADR) and to identify related risk factors; to explore the KDZI combination with other drugs in clinical practice; to study characteristic of KDZI's adverse drug reaction and anaphylactic reaction of KDZI by implanting a nested case control study.

**Method:** A multiple-center registry study based in seventeen hospitals with 30,000 patients is being conducted. And a nested case control study will also be inserted in this observational study.

**Study population:** Patients using KDZI during their hospitalization will be included from April 2012 to December 2014 in this study.

**Data collecting:** A registry form consists of three parts is used in this study. Part A is a one-page simple form containing patient background information and the administration of KDZI. Part B is a three pages form, used to report ADR when. Part C is a one-page form, extracting information from the hospital information system and Laboratory Information System.

All data will be collected in two ways, the first collecting will be conducted by case report form and the second collecting will be online recording.

### Biography

Xing Liao is an assistant researcher of Traditional Chinese Medicine. She had completed her Ph.D in July 2011, graduated from Beijing University of Chinese Medicine. She had education in clinical traditional Chinese medicine and evidence based Chinese medicine. At present, she is a core research member of the registry study on the safety surveillance of Chinese Medicine injection at China Academy of Chinese Medical Sciences. She is keen on study of pharmacovigilance and read a lot literature about the U.S FDA sentinel initiative.

okfrom2008@hotmail.com