

• 計畫中文名稱	以健保資料庫進行類風濕性關節炎病人使用 Tumor Necrosis Factor Inhibitor 之感染症分析		
• 計畫英文名稱	Claim Database Analysis of Infectious Diseases in Rheumatoid Arthritis Patients Treated with Tumor Necrosis Factor Inhibitors		
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• 研究人員	陳香吟,湯澡薰		
• 中文關鍵字	Etanercept ; Tumor Necrosis Factor Inhibitor ; 健保資料庫 ; 感染症 ; 藥物不良事件 ; 類風濕性關節炎		
• 英文關鍵字	Etanercept ; Tumor Necrosis Factor Inhibitor ; National Health Insurance Research Database ; Infection ; ADE ; RA		
• 中文摘要	<p>Etanercept (一種 Tumor Necrosis Factor (TNF) Inhibitor 類的生物製劑) 是全民健康 保險加強管控的藥品之一，需事前專案申請，適用條件嚴格，但儘管如此，中央健康 保險局 96 年仍在此單一藥物藥費上耗費 4.5 億。藥費尚不是藥物治療導致的資源耗用 中最大宗的。藥物相關的罹病與死亡每年導致的花費於五年內已經從 766 億美金暴增 為 1,774 億美金，因此，了解並且設法避免藥物相關的罹病與死亡是當前最重要的議題。 回顧國內外相關研究，以拓展使用市場為目的之有效性研究為主，少有專門設計 來探討此類藥物之安全性研究，更枉論專門探討相關感染不良反應。但感染症發生， 將帶來許多問題，後續處理又非停藥可解決，費用也較高需要積極探討。 本研究探討使用 TNF Inhibitors 治療類風濕性關節炎是否會增加感染相關不良事件 之風險。另外，亦比較兩種健保核定適用於治療類風濕性關節炎之 TNF Inhibitors，彼 此間是否有風險差異。本研究為 Cohort Study 設計，預計分析民國 92 年到 96 年，中央健保申報歸人檔 資料庫。除進行基礎之 2-tailed t tests 與 <math>\chi^2</math> tests 外，亦將計算研究追蹤期間總計之藥物 暴露，並以「Cox 傷害比例模式(Cox proportional hazards model)」分析比較兩組間各種 不良事件發生之 time-to-event 差異，以及分析兩組間不良事件發生之風險比率(risk ratios, RRs) 以及 95%信賴區間 (confidence interval, CIs)。</p>		
• 英文摘要	<p>of the drugs with reinforced control by the Bureau of National Health Insurance (BNHI). The criteria for its usage are very restricted and need a special application. In spite of all this bondages, BNHI medication expense of 2007 still was 4.5 hundred millions in this</p>		

single drug. The medication expenses are not the most resource consumed item caused by the medication treatment. The expenses caused by medication related diseases and death increased from 766 millions to 1,774 millions (US Dollars) within 5 years. Therefore, to understand and prevent the medication related diseases and death is an urgent and important issue. In a retrospective review of domestic and foreign researches, there are mainly effective researches for the expanding of the medication use market. Research designed to discuss drug safety are few, without mentioning research that discuss the adverse drug event related to infection. Once the infection occurs, it also brings out a lot of problems, and its resolution is not a single problem that ends withdrawing the drugs, the expenses are high. There is an urgent demand to discuss about this issue. The current study discusses the risk of increasing the adverse drug event related to infection in the treatment of Rheumatoid Arthritis using TNF Inhibitors. In the other hand, comparison of the risk difference between two TNF Inhibitors for Rheumatoid Arthritis approved by BNHI will also be realized. The current study is a Cohort Study, analyzing the Longitudinal Health Insurance Database 2005(LHID2005) from 2003 until 2007. Besides the analysis with 2-tailed t tests and  $\chi^2$  tests, during the follow up period, the total drug exposure time will be also calculated. By using Cox proportional hazards model, the current study also will compare the difference of time-to-event between the adverse drug events occurred in two groups and its risk ratios (RR) and the 95% confidence interval, (CIs).