CASE STUDY

A large Swiss cohort of patients with inflammatory bowel disease shifts from oral to intravenous iron supplementation therapy over time

CATEGORISING

Type:

BACKGROUND

In 2007, leading international experts in the field of inflammatory bowel disease recommended intravenous iron supplements over oral iron supplements because they were more effective and easier to tolerate.

METHODS

The Helsana insurance database provided data from adults (aged 18 or older) living in Switzerland, who suffered from Crohn's disease. Helsana is a Swiss health insurance company that covers 18% of the Swiss population (1.2 million individuals). Helsana anonymised data (stripping names, date of birth and address). Data were automatically generated at Helsana quarters, and required no additional manipulation. We analysed the data to determine what percentage of patients with inflammatory bowel disease was prescribed iron therapy, and described the dynamics of intravenous versus oral iron prescription.

QUESTIONS OF THE CATEGISER

Does the research project come under the scope of application of the Human Research Act?

No

BECAUSE

This project was based on a study protocol that defines the exact procedures to be used. It included a relatively large number of persons and was not based on individual cases ("method-driven search for generalizable knowledge", defined as research by HRA). The goal was to determine what percentage of patients with inflammatory bowel disease was prescribed iron therapy, and to describe the dynamics of intravenous versus oral iron prescription. The Helsana insurance database provided data from adults who lived in Switzerland and suffered from Crohn's disease ("health-related personal data"). Helsana's database was automatically generated, and required no additional manipulation. Data were anonymized by an independent institution (Helsana), not involved in the project and separated in time and space. The anonymised database did not include personal identifiers (insurance number, name, date of birth or address). This "research that involves anonymised health-related data" fell outside the scope of HRA.