

1. Abstract

Title

Post-marketing prospective, observational cohort study to evaluate the impact of AbbVie Care patient support program on compliance with adalimumab, patient reported outcomes and health resource utilization in inflammatory bowel diseases, rheumatoid arthritis, psoriatic arthritis, axial spondylarthritis and psoriasis in Portugal – IMPROVE Study

Keywords

AbbVie Care; Patient Support Program; Compliance;

Rationale and Background

This study would generate local evidence by investigating the impact of Abbvie Care 2.0 among patients that joined to this program, in outcomes such as compliance to adalimumab, patients' quality of life, satisfaction and utilization of health resources. This evidence will help to demonstrate the added value of AbbVie Care to the patients, HCPs and payers, and to the decision-making process.

A sample size of 131 patients per group was required, for a sampling power of 80% at a 95% significance level, yielding a sample size of 262 patients (292 patients with a drop out/non-evaluable correction of 10%).

The recruitment for IMPROVE study terminated on the 30th November 2018. The number of recruited patients was 116 vs 262 patients required to reach the protocol objectives.

A smaller sample size was statistically considered and evaluated, however the odds for success rates and robust data generation to demonstrate the effect of AbbVie Care program was unprovable.

Therefore, AbbVie decided to prematurely discontinue the study.

Research Question and Objectives

Does Abbvie Care provide additional benefit to patient's compliance to adalimumab, patient reported outcomes and utilization of health resources comparing to non-users of Abbvie Care in inflammatory bowel diseases, rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and psoriasis?

This post-marketing, prospective, observational, cohort study aimed to evaluate the impact of AbbVie Care 2.0 on patient's compliance to adalimumab comparing to non-users. The therapeutic indications covered by Abbvie Care 2.0 in this context included Inflammatory Bowel Diseases (Crohn's Disease and ulcerative colitis), Rheumatoid Arthritis (RA), psoriatic arthritis (PsA), axial spondyloarthritis (Axial SpA) and Psoriasis (Pso).

The impact of this PSP on patient-reported outcomes and health care resources utilization compared between Abbvie Care 2.0 users and Non-users were the secondary objectives.

Study Design

Multicentric, prospective, observational, cohort study, evaluated the impact of AbbVie Care on compliance to adalimumab, patient reported outcomes and health resources utilization compared with a cohort of non-users of AbbVie Care (control cohort). As part of the routine procedure at the participating investigational sites, all patients who have initiated adalimumab within 1 month prior to enrolment, according to physician clinical criteria, were invited to participate in the study.

The control cohort (non-users of Abbvie Care) consisted of patients who started adalimumab according to physician clinical criteria but did not accept to participate in the Abbvie Care 2.0 program.

It was expected to maintain a 1:1 ratio between cohorts throughout the recruitment period at each site.

The observation period for Abbvie Care cohort will be of 12 months (\pm 1 month) since the start of the program (baseline).

The observation period for the control cohort will be of 12 months (\pm 1 month), starting within 1 month after the introduction of adalimumab (baseline).

Setting

This study occurred in 9 Centers with a total of 26 investigators from Gastroenterology, Rheumatology, Dermatology and Pharmacy.

Subjects and Study Size, Including Dropouts

A total of 262 patients were planned (292 patients with a drop out/non-evaluable correction of 10%) to be enrolled, however the recruitment ended with 116 patients.

Data from all subjects fulfilling the selection criteria and with informed consent were included in this report.

Variables and Data Sources

The investigator recorded data in the CRF from no more than three visits during the 12-month observation period: Baseline, Month 6 and Month 12.

The following data were collected:

- Patient demographics (age, gender) - Baseline;

- Medical history (condition and date of diagnosis) - Baseline;
- Treatment history prior to adalimumab - Baseline;
- Start date of adalimumab and starting dose - Baseline;
- Period covered by physician's prescription of adalimumab (automatically registered during electronic prescription and was also recorded in the CRF) over 12 months;
- Dose change of adalimumab and date of change over 12 months; also specified intermittent treatments/treatment interruption and cause (e.g. due to surgery, infections, or other);
- Physician's Global Assessment of Disease Severity at baseline (100 mm Visual Analogue Scale from 0-no activity to 100-severe activity).
- Co-morbidities –Baseline, Month 6 and 12 (ongoing [yes/no]);
- BMQ – Baseline, Month 6 and 12;
- PAM-13 – Baseline and Month 12;
- Patient's satisfaction (TSQM-II) – Baseline, Month 6 and 12;
- Overall health quality of life (EQ-5D questionnaire) – Baseline, Month 6 and 12;
- Work productivity (WPAI-GH questionnaire), working status, number of days of sick leaves, number of sick leaves and time spent by the patient to refill prescription - Baseline and Month 6 and 12;
- Health resource utilization: number of hospital inpatient days; number of hospitalizations; number of emergency visits; number outpatient visits (in-office and remote) in hospital setting (ophthalmologist, gastroenterologist, dermatologist, physiatrist physiotherapist, rheumatology, nurse, etc.), time spent by the HCPs during medical appointments and number of complementary exams/techniques over 12 months;

- Concomitant medication and changes over 12 months, including combination therapy for the condition under investigation (e.g. methotrexate, corticosteroids, etc.) and reason for change;
- Serious Adverse Events (SAEs), AEs leading to the discontinuation of adalimumab, non-serious event of malignancy in patients ≤30 years of age and pregnancies over 12 months.

For Abbvie Care 2.0 Cohort only:

- Date of start of Abbvie Care 2.0 - Baseline;
- Components of the program initially administered to the patient (AbbVie Care 2.0 services questionnaire) - Baseline
- Overall evaluation of the level of use of Abbvie Care 2.0 by the patient (assessed by the Nurse using a 4 point Likert scale: 1- Good, 2- Reasonable, 3- Poor, 4- Not assessable) – Month 6 and 12.
- Patient overall satisfaction with AbbVie Care 2.0 program after 12 months (Likert scale: 1- Very good, 2- Good, 3- Less satisfying).
- For patients who decide to discontinue prematurely the AbbVie Care, the reason for discontinuation was documented.

Variables for assessment of compliance to adalimumab:

- Refill data from pharmacy records were used to calculate the variable MPR over 12 months. Whenever a physician prescribed adalimumab, this prescription was received electronically by the hospital pharmacy, including the name of the product, indication and posology. Each prescription of adalimumab is valid for a period of 3 or 6 months, depending on the physician's decision. At each clinical appointment, the physician renews prescription. Every month, patient visits the pharmacy to obtain new medication. In few hospitals in Portugal, the

prescription is not yet electronic, and the patients carries the prescription to the pharmacy (note: it is expected that the majority of participating sites will have an electronic prescription model).

- Number of injections of adalimumab administered based on patient diary over 12 months. All patients were provided with a patient diary in which they recorded the administrations of adalimumab. Every month, during the visit to the pharmacy to collect new medication, the patient was instructed to return the completed diary to the study staff and a new one was dispensed. Each diary covered a period of up to 1.5 months (to allow for delayed visit to the pharmacy) and patient registered the date of administration and any occurrences during injection. If necessary, at each visit the team re-trained the patient in the completion of the diary. The number of expected injections obtained from the CRF where the investigator recorded the dose and the period covered by the prescription concerned.

Variable for assessment of persistence with adalimumab

- Refill data from pharmacy records were used to calculate persistence with adalimumab. In the CRF, the physician recorded the period covered for each prescription of adalimumab. This allowed identifying cases of episodic therapy.

Use of Abbvie Care 2.0 components:

The core elements of Abbvie Care 2.0 are:

- Nursing support (helpline) and education services with injection training
- Starter kits and travel kits
- Provision of educational materials
- Disease awareness website
- Provision of sharps disposal containers

- Injection guide and reminders
- Home delivery and self-monitoring devices for gastro patients, only (IBDoc).

Results

Due to the very low number of subjects included into the study before premature termination, no analysis according to the criteria planned was possible. The respective statistical analysis is not conducted. Therefore, only descriptive statistics of available variables are presented in this report.

Discussion

Considering the very low number of subjects included into these analyses, no conclusions about this study endpoints were drawn from the data collected.