The BELTRIMS registry: a unique Belgian registry on real-world safety and efficacy data of MS patients treated with new DMTs in Belgium

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Introduction

In 2012, a working group from the Belgian Study Group for Multiple Sclerosis (BSGMS) created the first Belgian registry of multiple sclerosis (MS) patients, starting a new disease modifying treatment (DMT). No such independent registry existed in Belgium yet.

Aims

- Collect unbiased real life efficacy data as well as short and long term safety data of (new) immunoactive drugs in MS including:
  - Subgroups of patients such as > 55 years old, « treatment switch-over », …
  - Possible drug interactions
  - Pregnancy outcome
- Avoid dispersal of data in multiple dedicated registries

Ethical committee approval was obtained in 42 centers with fair representation of MS centers, university hospitals and general hospitals, Flemish and French speaking centers.

The registry is owned and managed by the BSGMS, with support of Custodix NV and is compliant with new European GDPR.

Inclusion criteria

- Patients starting a new DMT (since commercialization or since participation in a medical need program or phase IV study)
- Written informed consent (kept in patient file)

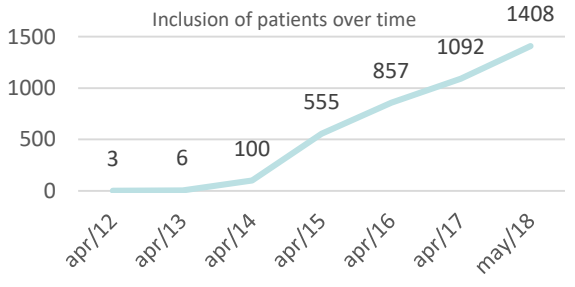
Exclusion criteria

- Patients participating in phase II or III trials
- Patients unable to give written informed consent

Methods

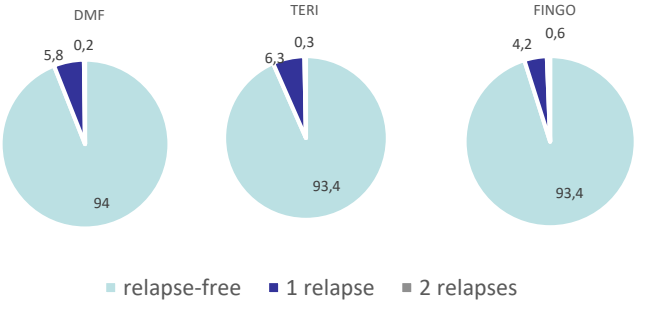
- Ongoing longitudinal observational registry
- Once a patient has been registered, follow up will be ongoing, even if the new treatment is stopped or switched
- Treatments and assessments are determined by the treating neurologist and dictated by clinical practice and available guidelines
- Participating neurologists are all members of the BSGMS and have expertise in treating MS patients and have EDSS-neurostatus certification
- Participation is on a voluntary basis
- Steering committee from the BSGMS decides on data analysis

1408 patients in the database (May 27, 2018) - 68,6% female

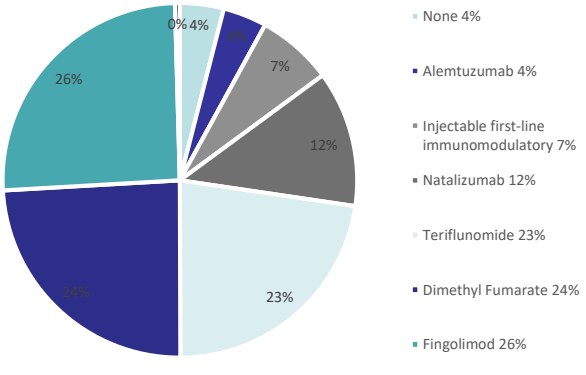


The estimated number of MS patients in Belgium is around 12,000 and 60% receive DMT[1]. This registry captures almost 20% of treated patients.

Percentage of patients without and with relapses according to treatment



Percentage of patients per treatment



Percentage of patients with worsening MRI

	DMF	TERI	FINGO
% of patients with worsening MRI	23,4	21,6	20,4
Gadolinium enhancement % among these patients	30	54	49
T2/Flair lesion increase % among these patients	62	72	80,4

Baseline data

	Fingolimod	DMF	Teriflunomide
Mean age (years)	42,9	42,7	46,3
Mean duration of disease (months)	120,5	112,5	140,52
Median EDSS	2,5	2	2,5
% of patients with prior treatment	93,6	74,2	82,7
% of patients with prior 2nd line treatment	25,9	10,02	2,7

SAE types per treatment

	Fingolimod (n=424)	Dimethylfumarate (n=376)	Teriflunomide (n=359)
SAE per drug treatment	21	7	10
SAE type			
Bacterial infection	2	1	2
Viral infection			1
Autoimmune disease	1	1	1
Cancer	5		
Cardiovascular	2	2	2
Ophtalmologic	1		
Other	10	3	4

Discussion

To date, this is the first and only Belgian MS registry. The current treatment practice of MS in Belgium is reflected in this registry. Challenges are finding incentives to enhance voluntary participation and to convince local health authorities to support this registry.
The registry is open for international collaborations (e.g. existing collaboration with iPRI).

Funding source: Grant from the Belgian Charcot Foundation

1: Data from http://www.emsp.org/wp-content/uploads/2015/08/MS-in-EU-access.pdf

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