

# FIELD FAST FACTS

The primary endpoint in FIELD was not met. However, fenofibrate significantly reduced cardiovascular and coronary events in primary prevention:

25% reduction in total CHD events (primary endpoint,  $p=0.014$ );

19% reduction in total CVD events (secondary endpoint,  $p=0.004$ ).

Fenofibrate positively impacts on diabetes-related renal and eye disease:

Significant reduction in progression to microalbuminuria (11% placebo vs 10% fenofibrate) ( $p < 0.002$ );

30% reduction in the need for laser treatment for retinopathy ( $p=0.0003$ ).

Fenofibrate was well tolerated:

81.6% of the fenofibrate arm remained on therapy compared to 81.5% of the placebo arm.

The FIELD study population was the largest group of primary prevention patients ever included in a Type 2 diabetes trial ( $n=7,664$ ).



# LATE BREAKING NEWS FIELD

## FIELD shows fenofibrate protects against major diabetes complications

Fenofibrate reduces the incidence of macrovascular and microvascular complications in people with type 2 diabetes, according to the landmark Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) trial presented today at the American Heart Association's 2005 Scientific Sessions in Dallas and published on-line in *The Lancet*.

“The study population was very representative of the patients we see in clinical practice,”

George Steiner, professor of medicine at the University of Toronto.



These results are the first from a large-scale clinical trial to show that a lipid-lowering agent can reduce both the macrovascular and microvascular complications of type 2 diabetes. The FIELD trial, based on nearly 10,000 patients, is the largest intervention study to assess the risk of cardiovascular disease in type 2 diabetes. Principal investigator Professor Anthony Keech said: "The FIELD trial is of great significance in the treatment of type 2 diabetes because it provides guidance on the use of fibrates in this rapidly growing group of patients."

Unlike other trials of lipid-lowering therapy in diabetes, FIELD participants' glycaemia was well controlled and many had nearly normal lipid levels. Very few suffered from diabetes-related eye or kidney disease. With a median duration of diabetes of 5 years, much of the population could be classified as being in the early stages of the disease.

## An important primary prevention treatment against secondary complications

People with diabetes are 2-4 times more likely to develop cardiovascular disease than people without diabetes. Yet in the FIELD trial, 78% of the men and women had no history of cardiovascular disease.

“There was a clear, significant benefit in the 78% of patients who were in the primary prevention group,”

Professor Keech.

In this subgroup – the vast majority of patients with type 2 diabetes – the effects of fenofibrate treatment were significantly larger. Among them, there was a 19% ( $p=0.004$ ) reduction in

total cardiovascular disease events – including myocardial infarction (MI), stroke and coronary revascularisation (angioplasty and bypass surgery) – and a 25% ( $p=0.014$ ) reduction in coronary events.

This is important as "the human and economic costs of diabetes could be significantly reduced by investing in prevention in order to avoid the onset of diabetic complications", according to the IDF.

“FIELD provides information to help guide clinicians on the future use of fenofibrate in patients with type 2 diabetes. The results are likely to be of particular importance among patients without previous cardiovascular disease and in settings where both the prevention of non-fatal macrovascular events and microvascular complications are judged important,” FIELD investigators.



## Macrovascular benefits

Fenofibrate was associated with 11% fewer major coronary events but this reduction was not statistically significant ( $p=0.16$ ). This was the primary outcome of the study. A post-hoc sub-group analysis on the primary outcome of coronary heart disease events showed that the patients with no evidence of CVD who were treated with fenofibrate had a significantly reduced incidence of non-fatal heart attack or coronary death. This subset of patients experienced a significant 25% reduction in non-fatal MI or coronary mortality ( $p=0.014$ ). However, this reduction was not noted in patients with previous cardiovascular disease.



“Although FIELD did not show a difference in the primary endpoint it gave us very important information. It told us that people who had not had a prior clinical cardiovascular event had a very definite reduction in coronary artery disease on fenofibrate treatment.”

Professor Steiner.

# Additional microvascular benefits demonstrated

*The FIELD trial is the first to show that fenofibrate reduced both the need for laser treatment for retinopathy and progression of albuminuria, a marker of renal disease. The FIELD investigators said changes in HbA1C levels, concomitant medications or minor reductions in blood pressure in the fenofibrate group did not explain this finding.*

Diabetes is the leading cause of blindness and visual impairment in adults in developed countries.

“The dramatic reduction in the need for laser therapy in the fenofibrate group suggests a protective effect that would be a very important new finding if further analysis confirms this,” Professor Keech.

“The FIELD trial has revealed a new and important observation; that fenofibrate may protect against microvascular complications, something that statins have not been shown to do,” Professor Steiner.



“The FIELD trial brings good data regarding the possibility of using the combination of a statin and fenofibrate to benefit diabetic patients,” Professor Michel Farnier, head of department of endocrinology and lipidology at the Point Médical clinic, Dijon, France.

## Use of statins

The trial protocol allowed treating physicians to initiate non-study lipid-lowering therapy (predominantly statins) during the course of the study. By the end of the study, twice as many patients in the placebo arm were receiving statins (32% versus 16%,  $p<0.0001$ ).

## Implications for clinical practice

“The risk of cardiovascular events is still high after statin therapy; 70% of the risk remains so anything we can do to further reduce this risk is worthwhile. Fenofibrate may well offer an opportunity to do this, in addition to reducing microvascular events,” Professor Keech.

“The treatment to prevent coronary disease in diabetes may well involve starting with a statin but then combining with fenofibrate. We know from FIELD that this is a safe combination,” Professor Steiner.

## The influence of statins in FIELD

*According to the investigators, statin use in FIELD may have had a "possible masking effect of [the benefit of] fenofibrate treatment" on reducing cardiovascular risk.*

The higher use of statins in the placebo group (32%) than in the fenofibrate group (16%) confounded the results of FIELD. Adjusting for

the higher statin use, the investigators concluded that the patients in the fenofibrate arm could have experienced a reduced risk of coronary heart disease events by 19 percent ( $p=0.01$ ) and of total cardiovascular disease events by 15 percent ( $p=0.004$ ) versus the 11 percent achieved in the study.

### DIABETES FAST FACTS

- ☉ Globally, 194 million people have diabetes, of which 90% have type 2 diabetes.
- ☉ Diabetes is the fourth main cause of death in most developed countries.
- ☉ People with type 2 diabetes have the same risk of heart attack as people without diabetes who have already had a heart attack.
- ☉ Strokes occur twice as often in people with diabetes and high blood pressure as in those with high blood pressure alone.
- ☉ The devastating complications of diabetes, such as blindness, kidney failure and heart disease, are imposing a huge burden on healthcare services. It is estimated that diabetes accounts for between 5% and 10% of a nation's health budget.

Source: International Diabetes Federation

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