Appendix - Inklusion och exklusions kriterier från D1690C00004

Inclusion criteria at enrolment (visit 1):	NDR	Läkemedelsregitret	Patientregistret
Provision of a written informed consent	NDR		
Diagnosed with type 2 diabetes	Alla med klintyp2 diabetes		
Men or women who are ≥18 years of age at time of consenting upon visit 1	Ålder >=18 år	Vid uttag av metformin A10BA02	
Women of childbearing potential (WOCBP) must be using an adequate method of contraception to avoid pregnancy throughout the study and for up to 4 weeks after the study in such manner that the risk of pregnancy is minimized. WOCBP include any female who has experienced menarche and who has not undergone successful surgical sterilization (hysterectomy, bilateral tubal ligation or bilateral oophorectomy) or is not postmenopausal (defined as amenorrhea ≥12 consecutive months; or women on hormone replacement therapy (HRT) with documented serum follicle stimulating hormone (FSH) level	Finns ej		

>35mIU/mL). Even women who are using oral, implanted or injectable contraceptive hormones or mechanical products such as an intrauterine device or barrier methods (diaphragm, condoms, spermicides) to prevent pregnancy or practicing abstinence or where partner is sterile (e.g., vasectomy), should be considered to be of child bearing potential. WOCBP must have a negative serum or urine pregnancy test (minimum sensitivity 25 IU/L or equivalent units of HCG) within 72 hours prior to the start of study medication.			
Treated with OAD therapy that includes metformin for at least 8 weeks prior to enrolment; NB In addition to metformin patients are only allowed to be on one further OAD and only up to the half maximum dose available. This applies both to the administration of the other OAD as separate drug or as fixed dose combination		Patienter på A10BA02 monoterapi	
Inclusion criteria at start of metformin dose-stabilisation period - if applicable (visit 2, laboratory values from visit 1):			

HbA1c >6.5% and ≤10.0%; NB Patients with HbA1c >6.5% to <7% will no longer be eligible when the cohort of randomised patients having HbA1c <7% isapproximately 25% and the lower bound of HbA1c for enrolment will be set at HbA1c ≥7% for the remainder of the study.	hba1c > 47 mmol/mol and <= 86 mmol/mol		
FPG ≤270 mg/dL (≤14.4 mmol/L) Fasting plasma glucose	Finns ej		
C-peptide level ≥1.0 ng/mL (≥0.375 nmol/L), är en biprodukt vid kroppens egen produktion av insulin	Finns ej		
Inclusion criteria at placebo lead-in period		Inclusion criteria at metformin lead-in period	
Treatment with metformin alone on a stable dose of 1500 mg/day up to 2500 mg/day for at least 8 weeks For patients who entered the study on a stable dose of metformin monotherapy ≥1500 mg/day with no other OAD therapy in the last 8 weeks and who skipped the metformin dose-stabilisation period (laboratory values from visit 1):	vi kan inte definiera en runinperiod	metformin, minst 2 uttag under 180 dagar före en NDR-registrering	

HbA1c >6.5% and ≤10.0%; NB Patients with HbA1c >6.5% to <7% will no longer be eligible when the cohort of randomised patients having HbA1c <7% is approximately 25% and the lower bound of HbA1c for enrolment will be set at HbA1c ≥7% for the remainder of the study.	hba1c > 47 mmol/mol and <= 86 mmol/mol		
FPG ≤270 mg/dL (≤14.4 mmol/L)	Finns ej		
C-peptide level ≥1.0 ng/mL (≥0.375 nmol/L)	Finns ej		
Inclusion criteria at randomisation (visit 5, laboratory values from visit 4):			
HbA1c >6.5% and ≤10.0%	hba1c > 47 mmol/mol and <= 86 mmol/mol		
FPG ≤270 mg/dL (≤14.4 mmol/L)	Finns ej		
For inclusion in the optional genetic research, patients must fulfil the following criterion			
Provision of written informed consent for genetic research	behövs ej		
Exclusion criteria at enrolment			

Type 1 diabetes, history of diabetic ketoacidosis or hyperosmolar non-ketonic coma, or corticosteroid-induced type 2 diabetes	klinisk typ 1 någonsin tidigare		**ICD10**: E10… Diabetes mellitus typ 1. Hypo with coma hypo_withcoma E100, E106A, E110, E110C, E110X, E116A, E120, E130, E140, E159, E160, E161W, E162, R402, E101, E111, E121, E131, E141, R739, eller NDR: kliniskt typ 1 , Hypo with coma: E10.0 Diabetes mellitus typ 1 med koma E10.0A Diabetes mellitus typ 1 med ketoacidotiskt koma E10.0B Diabetes mellitus typ 1 med hyperosmolärt koma E10.0C Diabetes mellitus typ 1 med hypoglykemiskt koma E10.0D Diabetes mellitus typ 1 med laktacidotiskt koma E10.0X Diabetes mellitus typ 1 med koma UN
History of diabetes insipidus			**ICD10:** E23.2 Diabetes insipidus
Symptoms of poorly controlled diabetes that would preclude participation in this trial including, but not limited to, marked polyuria and polydipsia with greater than 10% weight loss during the 3 months prior to enrolment, or other signs and symptoms.	Finns inte, svårt med weight loss på 3 månader		**ICD10:** R35… Polyuri (stor mängd urin) (R35). And R63.1 Polydipsi

History of unstable or rapidly progressing renal disease			**ICD10:** N17…, N18…, N19…, Z94.0, N08.3, Z49…, Y82.4
Known condition of congenital renal glucosuria			ICD10: R81.9 Glukosuri, E74.0 Glykogeninlagringssjukdom E74.1 Rubbningar i fruktosomsättningen E74.2 Rubbningar i galaktosomsättningen E74.3 Andra specificerade rubbningar i intestinal kolhydratresorption E74.4 Rubbningar i pyruvatomsättning och glukoneogenes E74.8 Andra specificerade rubbningar i kolhydratomsättningen E74.8A Renal glukosuri E74.8B Oxaluri E74.8W Annan specificerad rubbning i kolhydratomsättningen E74.9 Rubbning i kolhydratomsättningen, ospecificerad

History of severe hepatobiliary disease or hepatotoxicity with any medication			ICD10: 'B15' 'B16' 'B17' 'B18' 'B19', K70.1 Alkoholhepatit K71.2 Toxisk leversjukdom med akut hepatit K71.3 Toxisk leversjukdom med kronisk persisterande hepatit K71.4 Toxisk leversjukdom med kronisk lobulär hepatit K71.5 Toxisk leversjukdom med kronisk aktiv hepatit K71.6 Toxisk leversjukdom med hepatit som ej klassificeras annorstädes K73.0 Kronisk persisterande hepatit som ej klassificeras annorstädes K73.1 Kronisk lobulär hepatit som ej klassificeras annorstädes K73.2 Kronisk aktiv hepatit som ej klassificeras annorstädes K73.8 Annan specificerad kronisk hepatit som ej klassificeras annorstädes K73.9 Kronisk hepatit, ospecificerad K75.2 Icke specifik reaktiv hepatit K75.3 Granulomatös hepatit som ej klassificeras annorstädes K75.4 Autoimmun hepati, Z22.5 bärare av hepatitvirus

Pregnant or breastfeeding patients			ICD10: O… förutom Förlossning (O80-O84), Z33 graviditet O24.4 gestational diabetes , sätt ett graviditetsdatum 9 månader innan förlossning
Body mass index (BMI) >45.0 kg/m2	Ja, vid varje regdatum		
Insulin therapy within one year of enrolment (with the exception of insulin therapy during a hospitalization or use in gestational diabetes)		**ATC:** A10A… exkludera all som tagit ut insulin	
Previous participation in a clinical trial with dapagliflozin (BMS-512148) and/or with any other SGLT2 inhibitor	vi kan inte veta om patienterna har varit med i någon studie		
Treatment with glucocorticoids equivalent to oral prednisolone>10 mg (betametasone >1.2 mg/ dexametasone >1.5 mg/ hydrocortisone >40 mg)/day within 30 days prior to enrolment; topical or inhaled corticosteroids are allowed		uthämtningar 3 månader innan: **ATC:** H02AB…, R03BA…, A01AC03, A07EA02, C05AA01, D07AA02, D07XA01, H02AB09, S01BA02, S01CB03, S02BA01, D07AC16, D07CA01, S01CA03, S02CA03, S03CA04, D07BA04, S01BB01, D07AB11, D07AB02, D07BB04, R01AD60	
History of bariatric surgery			**ICD10: OPkod** JDF10, JDF11 GbP Fetmaoperationer JDF20 JDF03 JDF04 JDF00

Administration of weight loss medication, including but not limited to sibutramine, phentermine, orlistat, rimonabant, benzphetamine, diethylpropion, methamphetamine, and/or phendimetrazine, within 30 days prior to enrolment		**ATC:** A08AB01 - orlistat, A10BJ02 med namnet Saxenda är för fetma. Samma ATC-kod gäller också Victoza som har indikationen diabetes (gärna med övervikt och fetma). A08AA62, dvs en kombination av Bupropion och Naltrexon. A08AX01 Rimonabant fanns för ett antal år sedan A08AA10 likaså Dessa användes för behandling av fetma	
Treatment for Human immunodeficiency virus (HIV)/use of antiviral drugs (delavirdine, indinavir, nelfinavir, ritonavir, saquinavir) and/or known immunocompromised status, including patients who have undergone organ transplantation		**ATC:** J05AG02, J05AE02, J05AE04, J05AX66, J05AR10, J05AX67, J05AE03, J05AE01	ICD10: Sjukdom orsakad av humant immunbristvirus [HIV] (B20-B24) Sjukdom orsakad av humant immunbristvirus [HIV] tillsammans med infektions- och parasitsjukdom (B20), Akut HIV-infektionssyndrom (B23) Sjukdom orsakad av humant immunbristvirus [HIV] tillsammans med maligna tumörer (B21) Sjukdom orsakad av humant immunbristvirus [HIV] tillsammans med andra specificerade sjukdomar (B22) Icke specificerad sjukdom orsakad

			av humant immunbristvirus [HIV] (B24)
Intolerance, contraindication or potential allergy to metformin, dapagliflozin, glipizide, or placebo or formulation excepients	Finns ej	Finns ej	
Congestive heart failure defined as New York Heart Association (NYHA) class III or IV (see Appendix D, physical activity:), unstable congestive heart failure and/or left ventricular ejection fraction of ≤ 40%		Aldesteron i LMR, C03DA04-Eplerenon	ICD10: I50… Hjärtinsufficiens (I50)

Significant cardiovascular history within the past 6 months upon visit 1 defined as: myocardial infarction, unstable angina pectoris, transient ischemic attack, unstable or previously undiagnosed arrhythmia, cardiac surgery or revascularization (coronary angioplasty or bypass grafts), or cerebrovascular accident			AMI: 'I21' Unstable angina 'I20' TIA (transitoriska ischemiska attacker)'Z86.6A' 'G45.8' 'G45.9' unstable or previously undiagnosed arrhythmia, 'I44' 'I46' 'I47' 'I49' PCI: 'FNG02' 'FNG05' 'FNG10' 'FNG20' 'FNG22' 'FNG30' 'FNG96' CABG: 'FNA00' 'FNA10' 'FNA20' 'FNA96' 'FNB00' 'FNB20' 'FNB96' 'FNC10' 'FNC20' 'FNC30' 'FNC40' 'FNC50' 'FNC60' 'FNC96' 'FND10' 'FND20' 'FND96' 'FNE00' 'FNE10' 'FNE20' 'FNE96' 'FNF00' 'FNF10' 'FNF20' 'FNF30' 'FNF96' coronary revascularization Z95 cerebrovascular accident 'I60' 'I61' 'I62' 'I63' 'I64' 'I65' 'I66' 'I67' 'I68' 'I69'
Severe respiratory failure or severe emphysema			Kroniska sjukdomar i nedre luftvägarna (ej J45 Astma): Bronkit icke specificerad som akut eller kronisk (J40), Kronisk bronkit utan luftvägsobstruktion (J41) Icke specificerad kronisk bronkit (J42) Lungemfysem (J43) Kroniskt obstruktiv lungsjukdom [KOL] (J44) Akut svår astma (J46)

			Bronkiektasier (lokala utvidgningar av luftrören) (J47)
Severe uncontrolled hypertension defined as systolic blood pressure ≥180 mm Hg and/or diastolic blood pressure ≥110 mm Hg	ja finns i NDR. Vid varje regdatum		
Patients who, in the judgement of the Investigator, may be at risk for dehydration	nej	nej	nej
History of chronic haemolytic anaemia with the exception of sickle cell trait or thalassemia minor			ICD10: 'D5...', 'D6...', 'D7'... Sjukdomar i blod och blodbildande organ samt vissa rubbningar i immunsystemet, talassemi
History of alcohol abuse or illegal drug abuse within the past 12 months			ICD10: F10..., F11..., F12..., F13..., F14..., F15..., F16..., F17..., F18..., F19...
History of malignancy within the last 5 years, excluding successful treatment of basal or squamous cell skin carcinoma			ICD10 i PAR: C0-C9… cancer

Involvement in the planning and conduct of the study (applies to both AstraZeneca and Bristol-Myers Squibb staff or staff at the study centre)	nej		
Previous enrolment or randomisation to treatment in the present study	nej		
Participation in a clinical study during the last 90 days prior to visit 1	nej		
Donation of blood, plasma or platelets within the past 3 months prior to visit 1	nej		
Suspected or confirmed poor protocol or medication compliance as judged by the investigator	nej		
Exclusion criteria at start of metformin dose-stabilisation period (visit 2, laboratory values from visit 1):			
Renal failure or renal dysfunction (Creatinine-Clearance <60 ml/min)	ja vid varje regdatum i NDR, egfr < 60		
Urine albumin:creatinine ratio (UACR) >1,800 mg/g (>203.4 mg/mmol/Cr)	ja vid varje regdatum i NDR, makroalbuminuri		
Severe hepatic insufficiency and/or significant abnormal liver function defined as Aspartate aminotransferase (AST) >3 x upper limit of normal (ULN) and/or Alanine aminotransferase (ALT) >3 x ULN	nej, finnns ej i NDR		leversjukdomar 'K720' 'K721' 'K729' 'K746' 'K766' 'K767' 'R189' 'I850' 'I859' 'C220' 'Z944'

Serum total bilirubin (TB) >2 mg/dL (>34 µmol/L)	nej, finnns ej i NDR		
Creatine kinase (CK) >3 x ULN	nej, finnns ej i NDR		
Haemoglobin ≤11.0 g/dL (≤110 g/L) for men; haemoglobin ≤10.0 g/dL (≤100 g/L) for women	nej, finnns ej i NDR		anemi D50-D64 senaste året
Thyroid-stimulating hormone (TSH) values outside normal range, to be further confirmed by abnormal free T4 values	nej, finnns ej i NDR		
Positive serologic evidence of current infectious liver disease including patients being positive for Hepatitis B viral antibody IgM, Hepatitis B surface antigen and Hepatitis C virus antibody			ICD10: 'B15' 'B16' 'B17' 'B18' 'B19', K70.1 AlkoholhepatitK 71.2 Toxisk leversjukdom med akut hepatit K71.3 Toxisk leversjukdom med kronisk persisterande hepatit K71.4 Toxisk leversjukdom med kronisk lobulär hepatit K71.5 Toxisk leversjukdom med kronisk aktiv hepatit K71.6 Toxisk leversjukdom med hepatit som ej klassificeras annorstädes K73.0 Kronisk persisterande hepatit som ej klassificeras annorstädes K73.1 Kronisk lobulär hepatit som ej klassificeras annorstädes

			K73.2 Kronisk aktiv hepatit som ej klassificeras annorstädes K73.8 Annan specificerad kronisk hepatit som ej klassificeras annorstädes K73.9 Kronisk hepatit, ospecificerad K75.2 Icke specifik reaktiv hepatit K75.3 Granulomatös hepatit som ej klassificeras annorstädes K75.4 Autoimmun hepati, Z22.5 bärare av hepatitvirus
Any clinically significant abnormality identified on physical examination, ECG or laboratory tests, which in the judgement of the investigator would compromise the patients' safety or successful participation in the clinical study.	nej, finnns ej i NDR		ICD10: I20.9, I25.1 senaste året
For patients who entered the study on a stable dose of metformin monotherapy ≥1500 mg/day with no other OAD therapy in the last 8 weeks and who skipped the metformin dose-			

stabilisation period, exclusion criteria 29 - 37 will be checked at visit 4 (laboratory values from visit 1).			
Any clinically significant abnormality identified on physical examination or ECG, which in the judgement of the investigator would compromise the patients safety or successful participation in the clinical study	nej, finnns ej i NDR		ICD10: I20.9, I25.1 senaste året
For the participation in the optional genetic research, patients must not	behöver ej vara med		
Have had previous bone marrow transplant			ICD10: Z94.6 Benvävnadstransplanterad
Received blood transfusion in the 120 days preceding the date of genetic sampling collection. If either of these 2 exclusion criteria is present, the patient cannot participate in the optional blood sample donation.			ICD10: Z51.3 Blodtransfusion utan att diagnos anges

Inklusion och exklusions kriterier från NN2211-1572

Inclusion criteria:	NDR	Läkemedelsregistret	Patientregistret
Informed consent obtained before any trial-related activities (trial-related activities are any procedure that would not have been performed during normal management of the subject).	NDR		
Subjects diagnosed with type 2 diabetes and treated with OAD(s) for at least three months.	Alla med klintyp2 diabetes	A10B i tre månader, at least 2	
Age 18-80 years, both inclusive (as allowed according to local guidelines for metformin and glimepiride treatment).	Ålder >=18 år	First presciption of metformin A10BA02	
HbA1c (DCCT) − 7.0-10.0% (both incl.) in subjects on OAD combination therapy − 7.0-11.0% (both incl.) in subjects on OAD monotherapy..	7- 11 % HbA1c i NDR		
Body mass index (BMI) <= 40.0 kg/m2.	NDR		
Exclusion criteria			

Treatment with insulin within the last three months prior to trial (except for short-term treatment due to intercurrent illness at the discretion of the investigator).	ATC: A10A… exkludera all som tagit ut insulin prescription twice (look into data if it makes a difference)	**ATC:** A10A… exkludera all som tagit ut insulin prescription twice (look into data if it makes a difference)	

Impaired liver function, defined as alanine aminotransferase (ALAT) 2.5 times upper limit of normal (one retest analysed at the central laboratory within a week is permitted with the result of the last sample being conclusive).	Margit will check		ICD10: 'B15' 'B16' 'B17' 'B18' 'B19', K70.1 Alkoholhepatit K71.2 Toxisk leversjukdom med akut hepatit K71.3 Toxisk leversjukdom med kronisk persisterande hepatit K71.4 Toxisk leversjukdom med kronisk lobulär hepatit K71.5 Toxisk leversjukdom med kronisk aktiv hepatit K71.6 Toxisk leversjukdom med hepatit som ej klassificeras annorstädes K73.0 Kronisk persisterande hepatit som ej klassificeras annorstädes K73.1 Kronisk lobulär hepatit som ej klassificeras annorstädes K73.2 Kronisk aktiv hepatit som ej klassificeras annorstädes K73.8 Annan specificerad kronisk hepatit som ej klassificeras annorstädes K73.9 Kronisk hepatit, ospecificerad K75.2 Icke specifik reaktiv hepatit K75.3 Granulomatös hepatit som ej klassificeras annorstädes K75.4 Autoimmun hepati, Z22.5 bärare av hepatitvirus

Subjects known to be Hepatitis B antigen or Hepatitis C antibody positive	nej, finnns ej i NDR, Margit double checks codes		ICD10: leversjukdomar 'K720' 'K721' 'K729' 'K746' 'K766' 'K767' 'R189' 'I850' 'I859' 'C220' 'Z944'
Impaired renal function defined as serum creatinine >= 135 µmol/L (>= 1.5 mg/dL) for males and >= 110 µmol/L (>=1.3 mg/dL) for females (one retest analysed at the central laboratory within a week is permitted with the result of the last sample being conclusive) (due to a different conversion factor used by , the actual limits in mg/dL were ≥1.53 mg/dL for males and ≥1.24 mg/dL for females,	ja finns i NDR. Vid varje regdatum		
Clinically significant active cardiovascular disease including history of myocardial infarction within the past 6 months and/or heart failure (New York Heart Association class III and IV) at the discretion of the investigator (refer to Appendix C of the protocol).	Margit checks IDC codes		ICD10: AMI: 'I21' Unstable angina 'I20' TIA (transitoriska ischemiska attacker)'Z86.6A' 'G45.8' 'G45.9' unstable or previously undiagnosed arrhythmia, 'I44' 'I46' 'I47' 'I49' PCI: 'FNG02' 'FNG05' 'FNG10' 'FNG20' 'FNG22' 'FNG30' 'FNG96' CABG: 'FNA00' 'FNA10' 'FNA20' 'FNA96' 'FNB00' 'FNB20' 'FNB96' 'FNC10' 'FNC20' 'FNC30' 'FNC40' 'FNC50' 'FNC60' 'FNC96' 'FND10' 'FND20' 'FND96' 'FNE00' 'FNE10' 'FNE20' 'FNE96' 'FNF00' 'FNF10' 'FNF20' 'FNF30' 'FNF96' coronary

			revascularization Z95 cerebrovascular accident 'I60' 'I61' 'I62' 'I63' 'I64' 'I65' 'I66' 'I67' 'I68' 'I69'
Proliferative retinopathy or maculopathy requiring acute treatment as judged by the investigator.	ok		ICD10: H36.0 Diabetisk retinopati, H36.0A Icke proliferativ diabetsik retinopati, H36.0B proliferativ diabetsik retinopati, H36.0X Ospecifierad form av diabetsik retinopati
Uncontrolled treated/untreated hypertension (systolic blood pressure >=180 mmHg and/or diastolic blood pressure >= 100 mmHg)	ja finns i NDR. Vid varje regdatum		
Cancer (except basal cell skin cancer or squamous cell skin cancer) or any clinically significant disease or disorder, except for conditions associated to type 2 diabetes, which in the investigator's opinion could interfere with the results of the trial.	ok		ICD10 i PAR: C0-C9… cancer

Recurrent major hypoglycaemia as judged by the investigator.	ICD code major hypoglycemia at least twice		**ICD10**: E10… Diabetes mellitus typ 1. Hypo with coma hypo_withcoma E100, E106A, E110, E110C, E110X, E116A, E120, E130, E140, E159, E160, E161W, E162, R402, E101, E111, E121, E131, E141, R739, eller NDR: kliniskt typ 1 , Hypo with coma: E10.0 Diabetes mellitus typ 1 med koma E10.0A Diabetes mellitus typ 1 med ketoacidotiskt koma E10.0B Diabetes mellitus typ 1 med hyperosmolärt koma E10.0C Diabetes mellitus typ 1 med hypoglykemiskt koma E10.0D Diabetes mellitus typ 1 med laktacidotiskt koma E10.0X Diabetes mellitus typ 1 med koma UN
Known or suspected allergy to trial product(s) or related products	Impossible to capture in the data, Margit checks		

Use of any drug (except for OADs), which in the investigator's opinion could interfere with glucose levels (e.g. systemic corticosteroids).	Margit will check and think	ATC: H02AA, H02AB	Kroniska sjukdomar i nedre luftvägarna (ej J45 Astma): Bronkit icke specificerad som akut eller kronisk (J40), Kronisk bronkit utan luftvägsobstruktion (J41) Icke specificerad kronisk bronkit (J42) Lungemfysem (J43) Kroniskt obstruktiv lungsjukdom [KOL] (J44) Akut svår astma (J46) Bronkiektasier (lokala utvidgningar av luftrören) (J47)
Receipt of any investigational drug within the four weeks prior to this trial	skip		
Previous participation in the randomised phase of this trial. Re-screening is allowed once within the recruitment period.	skip		
Known or suspected abuse of alcohol or narcotics.	ok, Margit check		ICD10: F10..., F11..., F12..., F13..., F14..., F15..., F16..., F17..., F18..., F19...

Mental incapacity, unwillingness or language barrier precluding adequate understanding or cooperation	schizophrenia , down syndrom, mentally impaired, F70-79 Margit checks		
Females of childbearing potential who are pregnant, breast-feeding or intend to become pregnant or are not using adequate contraceptive methods (adequate contraceptive measures as required by local law or practice). This exclusion criterion has been modified in Germany according to Substantial Protocol Amendment No. 2-DE	10 month before delivery		ICD10: O… förutom Förlossning (O80-O84), Z33 graviditet O24.4 gestational diabetes , sätt ett graviditetsdatum 9 månader innan förlossning
Any contraindications to metformin or glimepiride (according to local requirements).	Skip		
Subjects with medical history of multiple endocrine neoplasia type 2 (MEN2) or familial medullary thyroid carcinoma (FMTC) if total thyroidectomy has not been performed or cannot be ensured (i.e. posterior capsule of the thyroid gland not removed).	ok		ICD10: E31.2 multiple endocrine neoplasia type 2 or Z83.41 familial medullary thyroid carcinoma (FMTC)
Removal of Patients from Therapy and Assessment			

Choose to withdraw from the trial at any time.	skip		
Be withdrawn from the trial at the discretion of the investigator or the sponsor, if judged non-compliant with the trial procedures or due to a safety concern	skip		
As stated in the protocol, subjects were to be withdrawn from the trial if the following applied:			
Pregnancy or intention of becoming pregnant	during the follow up (specialists)		
If self measured FPG on three consecutive days/occasions exceeded the limits set below, the subject was to contact the investigator and come in for an unscheduled visit as soon as possible. The next scheduled visit was not to be awaited. FPG was to be obtained and analysed by the central laboratory. If this FPG exceeded the limits set below and no treatable intercurrent cause for the hypoglycaemia had been diagnosed, the subject was to be withdrawn.	skip, ignored		

If any of the FPG samples analysed by the central laboratory exceeded the limits set below, the subject was to be immediately called in for an unscheduled visit as soon as the result had come to the knowledge of the investigator. The next scheduled visit was not to be awaited. A new FPG was to be obtained and analysed by the central laboratory. If this FPG exceeded the limits set below and no treatable intercurrent cause for the hypoglycaemia could be found, the subject was to be withdrawn.	skip		
Subjects titrated to less than 1500 mg metformin or more than 2000 mg metformin were to be withdrawn	skip		