Addition Of Januvia (Sitagliptin) Improves Glycemic Control In Patients Inadequately Controlled By Metformin (MK0431-078)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00545584

First received: October 16, 2007
Last updated: August 13, 2015
Last verified: August 2015
History of Changes

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Purpose

To compare the efficacy of three strategies of lifestyle changes associated with Januvia (sitagliptin) 100 mg/day in patients with Type 2 Diabetes Mellitus (T2DM) inadequately controlled by metformin (hemoglobin A1c [HbA1c] 6.5-9%). A difference between the three strategies of lifestyle changes was expected.

Condition	Intervention	Phase
Diabetes Mellitus, Non-Insulin-Dependent	Drug: sitagliptin phosphate Behavioral: Comparator: Diet Behavioral: Comparator: Physical Activity	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Multicenter, Open, Pragmatic, Randomized Trial Comparing the Efficacy of 3 Different Lifestyle Interventions After Addition of Sitagliptin to Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Metformin Therapy

Resource links provided by NLM:

MedlinePlus related topics: Health Checkup

Drug Information available for: Sitagliptin Sitagliptin phosphate

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Hemoglobin A1c Measurement [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  Hemoglobin A1c (HbA1c) is a measure of glycated hemoglobin in the blood. HbA1c greater than 6.5% was considered inadequately controlled.

Secondary Outcome Measures:

- Fasting Plasma Glucose (FPG) Measurement [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  Generally FPG values of ~5.0-7.2 mmol/L would be considered goal (American Diabetes Association).

Enrollment:	1512
Study Start Date:	April 2007
Study Completion Date:	November 2009
Primary Completion Date:	November 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sitagliptin with Standard of Care Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: No specific intervention (standard recommendation) on physical exercise and diet.	Drug: sitagliptin phosphate sitagliptin 100 mg once daily. Duration of treatment: 26 Weeks
Experimental: Sitagliptin with Diet Advice Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: Intervention on diet which includes advice on diet with a leaflet and a diary	Drug: sitagliptin phosphate sitagliptin 100 mg once daily. Duration of treatment: 26 Weeks Behavioral: Comparator: Diet Diet
Experimental: Sitagliptin with Diet and Physical Activity Advice Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: Intervention on diet + physical activity which includes advice on diet and physical activity with leaflets and diaries PLUS advice on physical activity with the utilization of a pedometer: subjects were asked to walk 10,000 steps per day 5 or more days per week.	Drug: sitagliptin phosphate sitagliptin 100 mg once daily. Duration of treatment: 26 Weeks Behavioral: Comparator: Diet Diet Behavioral: Comparator: Physical Activity Physical Activity

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Man or woman aged >/= 18 years,with T2DM and treated with the maximal tolerated dose of metformin, with documented or high likely inadequate control of diabetes (HbA1c 6.5-9%)

Exclusion Criteria:

- Daily insulin treatment or one insulin dose or more within the last 8 weeks or expected insulin treatment within the next 3 months.

- Hypoglycemia unawareness or recurrent major hypoglycemia or history of acidoketosis
- Known hypersensitivity or contraindication to metformin

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00545584

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Additional Information:

MedWatch - FDA maintained medical product safety Information EXIT

Merck: Patient & Caregiver U.S. Product Web Site EXIT

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00545584 History of Changes
Other Study ID Numbers:	0431-078 2007_023
Study First Received:	October 16, 2007
Results First Received:	April 19, 2011
Last Updated:	August 13, 2015
Health Authority:	France: Ministry of Health

Additional relevant MeSH terms:

Diabetes Mellitus	Hormones
Diabetes Mellitus, Type 2	Hormones, Hormone Substitutes, and Hormone Antagonists
Endocrine System Diseases	Hypoglycemic Agents
Glucose Metabolism Disorders	Incretins
Metabolic Diseases	Molecular Mechanisms of Pharmacological Action
Sitagliptin	Pharmacologic Actions
Dipeptidyl-Peptidase IV Inhibitors	Physiological Effects of Drugs
Enzyme Inhibitors	Protease Inhibitors

ClinicalTrials.gov processed this record on April 13, 2016

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Results First Received: April 19, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Diabetes Mellitus, Non-Insulin-Dependent
Interventions:	Drug: sitagliptin phosphate Behavioral: Comparator: Diet Behavioral: Comparator: Physical Activity

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
1512 subjects were selected/screened, 380 subjects failed screening, leaving 1132 subjects who were randomized.

Reporting Groups

	Description
Sitagliptin With Standard of Care	Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: No specific intervention (standard recommendation) on physical exercise and diet.
Sitagliptin With Diet Advice	Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: Intervention on diet which includes advice on diet with a leaflet and a diary
Sitagliptin With Diet and Physical Activity Advice	Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: Intervention on diet + physical activity which includes advice on diet and physical activity with leaflets and diaries PLUS advice on physical activity with the utilization of a pedometer: subjects were asked to walk 10,000 steps per day 5 or more days per week.

Participant Flow: Overall Study

	Sitagliptin With Standard of Care	Sitagliptin With Diet Advice	Sitagliptin With Diet and Physical Activity Advice
STARTED	**412**	**414**	**306** [1]
COMPLETED	**333**	**334**	**250**
NOT COMPLETED	**79**	**80**	**56**
Only one reason for discontinuation	**62**	**61**	**48**
Two or more reasons for discontinuation	**17**	**19**	**8**

[1] 306 subjects were randomized but only 305 were treated.

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Sitagliptin With Standard of Care	Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: No specific intervention (standard recommendation) on physical exercise and diet.
Sitagliptin With Diet Advice	Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: Intervention on diet which includes advice on diet with a leaflet and a diary
Sitagliptin With Diet and Physical Activity Advice	Subjects received sitagliptin 100 mg once daily for 26 Weeks, and:

	Intervention on diet + physical activity which includes advice on diet and physical activity with leaflets and diaries PLUS advice on physical activity with the utilization of a pedometer: subjects were asked to walk 10,000 steps per day 5 or more days per week.
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin With Standard of Care	Sitagliptin With Diet Advice	Sitagliptin With Diet and Physical Activity Advice	Total
Number of Participants [units: participants]	**362**	**358**	**265**	**985**
Age [1] [units: years] Mean (Standard Deviation)	**58.26 (10.04)**	**57.47 (9.12)**	**57.30 (9.90)**	**57.71 (9.68)**
Gender [1] [units: participants]				
Female	**181**	**175**	**126**	**482**
Male	**181**	**183**	**139**	**503**

[1] The Full Analysis Set (FAS) population included all selected patients with at least one measured HbA1c value after Visit 2 and having received at least one dose of sitagliptin.

Outcome Measures

Hide All Outcome Measures

1. Primary: Hemoglobin A1c Measurement [Time Frame: Baseline and Week 24]

Measure Type	Primary
Measure Title	Hemoglobin A1c Measurement
Measure Description	Hemoglobin A1c (HbA1c) is a measure of glycated hemoglobin in the blood. HbA1c greater than 6.5% was considered inadequately controlled.
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) population included all selected patients with at least one measured HbA1c value after Visit 2 and having received at least one dose of sitagliptin. In the Standard of Care group, only 360 subjects had HbA1c Baseline evaluations.

Reporting Groups

	Description
Sitagliptin With Standard of Care	Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: No specific intervention (standard recommendation) on physical exercise and diet.

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Sitagliptin With Diet and Physical Activity Advice	Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: Intervention on diet + physical activity which includes advice on diet and physical activity with leaflets and diaries PLUS advice on physical activity with the utilization of a pedometer: subjects were asked to walk 10,000 steps per day 5 or more days per week.

Measured Values

	Sitagliptin With Standard of Care	Sitagliptin With Diet Advice	Sitagliptin With Diet and Physical Activity Advice
Number of Participants Analyzed [units: participants]	**362**	**358**	**265**
Hemoglobin A1c Measurement [units: percent HbA1c] Mean (Standard Deviation)			
Baseline (n=360, 358, and 265, respectively)	**7.37 (0.61)**	**7.50 (0.66)**	**7.49 (0.60)**
Week 24 (n=362, 358, and 265, respectively)	**7.33 (1.09)**	**7.42 (1.15)**	**7.40 (1.07)**

No statistical analysis provided for Hemoglobin A1c Measurement

2. Secondary: Fasting Plasma Glucose (FPG) Measurement [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Fasting Plasma Glucose (FPG) Measurement
Measure Description	Generally FPG values of ~5.0–7.2 mmol/L would be considered goal (American Diabetes Association).
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
FAS population. Furthermore, only 350, 252, and 350 subjects had FPG evaluations in the Diet advice, Diet & physical activity advice, and Standard groups, respectively, at Baseline; and 303, 224, and 310 subjects had FPG evaluations in the Diet advice, Diet & physical activity advice, and Standard groups, respectively, at Week 24.

Reporting Groups

	Description
Sitagliptin With Standard of Care	Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: No specific intervention (standard recommendation) on physical exercise and diet.

Sitagliptin With Diet Advice	Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: Intervention on diet which includes advice on diet with a leaflet and a diary
Sitagliptin With Diet and Physical Activity Advice	Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: Intervention on diet + physical activity which includes advice on diet and physical activity with leaflets and diaries PLUS advice on physical activity with the utilization of a pedometer: subjects were asked to walk 10,000 steps per day 5 or more days per week.

Measured Values

	Sitagliptin With Standard of Care	Sitagliptin With Diet Advice	Sitagliptin With Diet and Physical Activity Advice
Number of Participants Analyzed [units: participants]	**310**	**303**	**224**
Fasting Plasma Glucose (FPG) Measurement [units: mmol/L glucose] Mean (Standard Deviation)			
Baseline (n=350, 350, 252, respectively)	**8.87 (1.98)**	**9.00 (2.03)**	**8.91 (1.87)**
Week 24 (n=310, 303, and 224, respectively)	**8.21 (2.07)**	**8.32 (2.08)**	**8.47 (2.17)**

No statistical analysis provided for Fasting Plasma Glucose (FPG) Measurement

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	This safety data includes AEs and SAEs that occurred during treatment (Visit 2 to Visit 4).
Additional Description	No text entered.

Reporting Groups

	Description
Sitagliptin With Standard of Care	Subjects received sitagliptin 100 mg once daily for 26 Weeks, and: No specific intervention (standard recommendation) on physical exercise and diet.
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Serious Adverse Events

	Sitagliptin With Standard of Care	Sitagliptin With Diet Advice	Sitagliptin With Diet and Physical Activity Advice
Total, serious adverse events			
# participants affected / at risk	**8/412 (1.94%)**	**18/414 (4.35%)**	**7/305 (2.30%)**
Blood and lymphatic system disorders			
IDIOPATHIC THROMBOCYTOPENIC PURPURA † 1			
# participants affected / at risk	**1/412 (0.24%)**	**0/414 (0.00%)**	**0/305 (0.00%)**
# events	**1**	**0**	**0**
Cardiac disorders			
ACUTE CORONARY SYNDROME † 1			
# participants affected / at risk	**1/412 (0.24%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**1**	**1**	**0**
ADAMS-STOKES SYNDROME † 1			
# participants affected / at risk	**1/412 (0.24%)**	**0/414 (0.00%)**	**0/305 (0.00%)**
# events	**1**	**0**	**0**
ANGINA UNSTABLE † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
MYOCARDIAL INFARCTION † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
Eye disorders			
MACULAR OPACITY † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
Gastrointestinal disorders			
INGUINAL HERNIA † 1			
# participants affected / at risk	**1/412 (0.24%)**	**0/414 (0.00%)**	**0/305 (0.00%)**
# events	**1**	**0**	**0**
General disorders			
CARDIAC DEATH † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
SUDDEN DEATH † 1			
# participants affected / at risk	**1/412 (0.24%)**	**0/414 (0.00%)**	**0/305 (0.00%)**
# events	**1**	**0**	**0**
Hepatobiliary disorders			
CHOLECYSTITIS † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
Infections and infestations			

ABDOMINAL WALL ABSCESS † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
EAR INFECTION † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
LARYNGITIS † 1			
# participants affected / at risk	**1/412 (0.24%)**	**0/414 (0.00%)**	**0/305 (0.00%)**
# events	**1**	**0**	**0**
PNEUMONIA † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
Injury, poisoning and procedural complications			
DRUG EXPOSURE DURING PREGNANCY † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
FRACTURE † 1			
# participants affected / at risk	**0/412 (0.00%)**	**0/414 (0.00%)**	**1/305 (0.33%)**
# events	**0**	**0**	**1**
LIMB TRAUMATIC AMPUTATION † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
LUMBAR VERTEBRAL FRACTURE † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
TENDON RUPTURE † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
Metabolism and nutrition disorders			
DIABETES MELLITUS † 1			
# participants affected / at risk	**1/412 (0.24%)**	**0/414 (0.00%)**	**0/305 (0.00%)**
# events	**1**	**0**	**0**
Musculoskeletal and connective tissue disorders			
OSTEOARTHRITIS † 1			
# participants affected / at risk	**0/412 (0.00%)**	**0/414 (0.00%)**	**1/305 (0.33%)**
# events	**0**	**0**	**1**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BREAST CANCER † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
FIBROMA † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
† 1			

LUNG NEOPLASM MALIGNANT			
# participants affected / at risk	**0/412 (0.00%)**	**0/414 (0.00%)**	**1/305 (0.33%)**
# events	**0**	**0**	**1**
PROSTATE CANCER † 1			
# participants affected / at risk	**0/412 (0.00%)**	**0/414 (0.00%)**	**2/305 (0.66%)**
# events	**0**	**0**	**2**
Nervous system disorders			
CERVICAL ROOT PAIN † 1			
# participants affected / at risk	**0/412 (0.00%)**	**0/414 (0.00%)**	**1/305 (0.33%)**
# events	**0**	**0**	**1**
ENCEPHALITIS † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
SCIATICA † 1			
# participants affected / at risk	**0/412 (0.00%)**	**0/414 (0.00%)**	**1/305 (0.33%)**
# events	**0**	**0**	**1**
SYNCOPE † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
Psychiatric disorders			
DEPRESSION † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
SUICIDE ATTEMPT † 1			
# participants affected / at risk	**1/412 (0.24%)**	**0/414 (0.00%)**	**0/305 (0.00%)**
# events	**1**	**0**	**0**
Renal and urinary disorders			
RENAL NECROSIS † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
Reproductive system and breast disorders			
GENITAL PROLAPSE † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**
Respiratory, thoracic and mediastinal disorders			
PULMONARY EMBOLISM † 1			
# participants affected / at risk	**1/412 (0.24%)**	**0/414 (0.00%)**	**0/305 (0.00%)**
# events	**1**	**0**	**0**
Skin and subcutaneous tissue disorders			
RASH † 1			
# participants affected / at risk	**0/412 (0.00%)**	**1/414 (0.24%)**	**0/305 (0.00%)**
# events	**0**	**1**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 12.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	This safety data includes AEs and SAEs that occurred during treatment (Visit 2 to Visit 4).
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

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Other Adverse Events

	Sitagliptin With Standard of Care	**Sitagliptin With Diet Advice**	**Sitagliptin With Diet and Physical Activity Advice**
Total, other (not including serious) adverse events			
# participants affected / at risk	**0/412 (0.00%)**	**0/414 (0.00%)**	**0/305 (0.00%)**

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00545584 History of Changes
Other Study ID Numbers:	0431-078 2007_023
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Health Authority:	France: Ministry of Health

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